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A systematic review of self-report measures of depression, suitable for use with people with progressive neurological conditions

And

An examination of the relationship between psychological flexibility and loneliness in older adults.

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Deirdre Holly

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Chapter 1 – Thesis Portfolio Abstracts

Portfolio Abstract

Background: Ageing is associated both with a higher likelihood of developing a progressive neurological condition, such as dementia, or for a neurological condition such as MS to deteriorate. The impact of these on social relationships and on depression are likely, and yet reliable measurement in this area is not well developed. This thesis therefore sought to contribute to research and practice in this field by reviewing available measures of depression for people with neurological conditions, and assessing relationships between age, loneliness, interpersonal difficulties and psychological flexibility.

Methods: A systematic review of studies assessing the validity and reliability of self-report measures of depression for use with people with progressive neurological conditions was carried out. The studies were quality assessed using COSMIN criteria. Findings of studies were pooled to allow overall recommendations about the use of the identified measures to be made.

A cross-sectional study was carried out with older adults using standardised measures to identify the relationship between loneliness and psychological flexibility and the subsequent impact on anxiety, depression and quality of life. A step-by-step process was used to develop statistical models of these relationships. Conditional process analysis was used to identify mediating and moderating factors in these relationships.

Results: The systematic review identified 14 studies assessing the validity and reliability of six different measures. The approaches used to assess the validity and reliability of measures varied, as did the quality of the evidence. It is suggested that the Geriatric Depression Scale may be the most appropriate self-report measure for use with people with progressive neurological conditions.

Regression analysis showed that loneliness, interpersonal difficulties, attachment anxiety and psychological flexibility were significant predictors of anxiety, depression and quality of life.

Using conditional process analysis, psychological flexibility significantly moderated the relationships between attachment anxiety and the outcome variables.

Conclusion: Recommendations for how validation studies could be improved are made, in the hopes that this may allow those carrying out future reviews to be able to draw sound conclusions from a larger body of evidence.

Psychological flexibility may play an important role in the mitigation of loneliness in older adults and may help protect against the development of mental health difficulties.

Lay Summary

Literature review

Progressive neurological conditions include muscle disorders and more specific conditions such as Motor Neuron Disease and Parkinson's disease. We know that people with these conditions are more likely to have depression, which can influence how well they follow advice given by health professionals but also how well they feel they are doing day-to-day. Guidelines for health professionals say that it is important to take into consideration a person with a PNC's mental health, however, they do not say how this should be done. To answer this question, a review of the literature was carried out to identify papers that had assessed how well measures can assess depression within these populations. Thirteen papers were identified, which looked at six different measures. Some of the studies were of a better quality than others. From the available studies, it would seem that the Geriatric Depression Scale may be the best measure to use, because it has been the most well researched and has the most evidence to suggest that it would be useful for helping identify depression.

Research study

This study was carried out to identify the factors that influence loneliness in older adults (age 60+) to see how loneliness can impact a person's quality of life as well as their mental health. In particular we wanted to know whether psychological flexibility influences people's ability

to make and maintain relationships and to buffer against feelings of loneliness. Psychological flexibility is our ability to be self-aware, open to thoughts and feelings and to engage in activities that matter to us. We asked older adults to complete a number of questionnaires about how they feel in relationships, and whether they are lonely, along with questionnaires about psychological flexibility, anxiety, depression and quality of life. The results of the study suggest that people who find relationships difficult and feel lonely are more likely to feel anxious or depressed, which also has an impact on their quality of life. We also found that a person's level of psychological flexibility can influence the impact of these relationships. This suggests that we should be trying to increase older adult's psychological flexibility in order to help reduce the impact that difficult relationships and loneliness can have on their mental health.

Chapter 2 – Systematic Review

Title: A systematic review of self-report measures of depression, suitable for use with people with progressive neurological conditions

Authors: Deirdre Holly[1, 2], Fiona Beaton[1, 2] David Gillanders[2]

Affiliation: [1]Dept. of Psychological Services & Research, NHS Dumfries & Galloway [2]School of Health and Social Science, University of Edinburgh

Mailing address: Dept. of Psychological Services & Research, Mountainhall Treatment Centre, Bankend Road, DG1 4GG

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Abstract

Background: People with progressive neurological conditions are more likely than the general population to experience depression. Guidelines state that depression should be assessed and monitored but do not state which measures are suitable for this purpose.

Method: A systematic review was carried out, and identified measures were evaluated using COSMIN criteria. Literature searches of PsycINFO, Medline, Scopus, Web of Science, CINAHL and the Cochrane Central Register of Controlled Trials (CENTRAL) were undertaken between December 2019 and April 2020.

Results: 13 papers were included. Most papers included people with Parkinson's disease. Six different measures were identified, the most well researched was the Geriatric Depression Scale. The evidence to support the validity and reliability of the measures varied. The most frequently explored areas of validity and reliability were internal consistency, construct validity and criterion validity.

Conclusion: Recommendations for use of the measures in clinical practice and research are made.

Key words: assessment, measurement, depression, progressive neurological condition, self-report, reliability, validity

Introduction

Progressive neurological conditions (PNC) include a variety of conditions such as Motor Neuron Disease (MND), Lou Gehrig's Disease, Huntington's disease (HD), Parkinson's disease (PD) and Multiple Sclerosis (MS) to name a few. All of these conditions involve uncertainty and incurability, and have implications for a person being able to live independently due to a likelihood of deteriorating function. In terms of the prevalence of some of these conditions worldwide, estimates are as follows: 7.4% for Parkinson's disease and 7.4% for Multiple Sclerosis (Vos et al., 2015). While HD and MS typically appear when someone is aged 30-50, onset of PD tends to be later in life. Symptoms common amongst all can be classed as motor (e.g. gait and balance disorders), psychological (e.g. anxiety, depression, apathy, fatigue) and neurological (e.g. cognitive impairment) (Bachoud-Levi et al., 2019; Mitchell et al., 2005).

Depression is a condition typically marked by low mood or sadness as well as loss of interest and pleasure in usual activities. In addition, common features also include apprehension, feelings of worthlessness and guilt, withdrawal from others, disturbed appetite and sleep, loss of libido, and either lethargy or agitation. In the general population, it is estimated that approximately 11% suffer from major depressive disorder (Vos et al., 2015). However, rates within populations with PNC are considerably higher. Prevalence rates for depression within a HD population vary from 33-69% (Van Duijn et al., 2007). Within a PD population, about 35% have clinically significant symptoms of depression (Timmer et al., 2017). Up to 50% of people with MS (Patten et al., 2017) may experience depression. Depression can influence quality of life as well as adherence to treatment. In particular, it has been suggested that depression may have a greater impact on a person with MS, than the biological symptoms of the condition (Mitchell et al., 2005). Furthermore, it may also exacerbate symptoms of

cognitive decline (Sachs-Ericcson et al., 2005). Depression may also be a consequence of the physical and neurological aspects of these conditions, such as spasms or myoclonus, thus it is likely that psychological and physical symptoms may be somewhat intertwined (Mitchell et al., 2005). 523593

National Institute of Health and Care Excellence (NICE) guidelines for PD (NICE, 2017) and MS (NICE, 2019) state the importance of being able to identify and treat depression within these populations, however, they refer users to the NICE Guideline on Depression in Adults with Chronic Physical Health Conditions (NICE, 2009). These guidelines state that "When assessing a patient with suspected depression, consider using a validated measure (for example, for symptoms, functions and/or disability) to inform and evaluate treatment" (point 1.3.1.4; NICE 2009, p.19). Despite this, no suggestion is given about what measures may be most suitable. Similarly, International Guidelines for the Treatment of Huntington's Disease state "Vigilance to detect and treat depression is required at all stages of the disease," but again does not offer any recommendations as to how this should be implemented (Bachoud-Lévi et al., 2019, p.7).

It is important that a measure of depression is validated for a population prior to its use, to ensure that it is fit for purpose and will not potentially misclassify someone, especially given that many self-report measures of depression (e.g. Beck Depression Inventory) include somatic symptoms that may also be features of PNC. The use of a questionnaire featuring somatic symptoms may result in a person being misclassified as either having or not having depression and thus may delay them receiving the support and intervention that they require. In addition, it is important to ensure that people with PNC are capable of completing these measures, for instance that they are not too demanding, and that the information gathered

is meaningful to both the person and those working with them. In the case of people with some forms of PNC, such as HD, limited research has been carried out to identify which self-report measures of depression may be most appropriate, thus it may be beneficial to examine various conditions in order to be able to generalise findings. Given that PNC share a number of characteristics, it may be appropriate to examine the validity and reliability of measures used with these populations as a whole.

There have been reviews of depression measures in people with MS (Patrick & Connick, 2019) and PD (Torbey et al., 2015). However, they do not appear to take into account the cognitive impact of these conditions. In addition, the measures identified are a combination of self-report and those administered by others. As of yet, no attempt has been made to examine the validity and reliability of self-report measures of depression across PNC to inform research and practice for those less well researched conditions. The benefit of using self-report measures is that they can be administered and scored by people who are not mental health specialists, who may come into contact with people with PNC on a more regular basis.

The validity of a measure is "the degree to which evidence and theory support the interpretations of test scores entailed by the proposed use of tests" (American Educational Research Association, American Psychological Association & National Council on Measurement in Education, 1999). Validity is a property of an inference and not an instrument, thus proposals to use a measure within a population in which it has previously not been used, require validity to be established within this new population to see whether those same inferences may be drawn.

The process of establishing the validity of a measure requires calculating its associated sensitivity and specificity compared to the population prevalence as defined by the gold standard measure. The closer the sensitivity and specificity are to 1.0 the greater the accuracy of the tool relative to a gold standard criterion. Associated with sensitivity and specificity is a measure's positive predictive value and negative predictive value (Altman & Bland, 1994).

There are various approaches that can be used to demonstrate validity, which can be classed as translation or criterion-related (American Educational Research Association, American Psychological Association & National Council on Measurement in Education, 1999). Criterion-related validity consists of four types of validity:

1. Predictive: The ability of a measure to predict something that theoretically it should be able to.
2. Concurrent: The degree to which a measure corelates with an existing measure of the same construct.
3. Convergent: The degree to which a measure corelates with measures of different constructs that the measure should theoretically be related to.
4. Discriminant: The extent to which the measure is not associated with constructs that it would not be theoretically predicted to correlate with.

In addition to the above, it is important to examine the following aspects of a measure:

- Construct validity: The extent to which a measure tests what it claims to test.
- Internal consistency: The degree to which questions in a measure are related to each other.

- Responsiveness: The ability of a measure to detect change, for instance, as a result of intervention.

Structural validity, the degree to which scores on aspects of a measure reflect the overall measure can be assessed via Classical Theory Testing (CTT) or Item Response Theory (CTT) or Rasch Theory (RT). CTT refers to the analysis of overall scores on a measure/test based on scores on individual items and takes into account item difficulty and item discrimination (Wu et al., 2016). Whereas IRT refers to the assessment of relationships between scores assigned to an item and the overall condition being measured. Lastly, Rasch focuses on the trade-off between a person's ability to answer questions and the difficulty of those questions (Wu & Adams, 2007).

Reliability refers to the ability of a test to produce the same results across different contexts and with different populations at multiple points in time. Internal consistency is a key aspect of reliability and refers to the extent to which individual items of a scale contribute relatively equally to the measurement of the underlying construct (Nunnally & Bernstein, 1994).

Aim and objectives

The aim of this systematic review was to evaluate the validity and reliability of self-report measures of depression for use by people with PNC, in order to generate recommendations for measurement in research and clinical practice.

Objectives:

1. To review the methodological quality of studies on measurement properties, using the **CO**nsensus-based **S**tandards for the selection of health **M**easurement **IN**struments (COSMIN) criteria (Terwee et al., 2018),
2. To review the findings of studies in relation to the psychometric properties of the instruments under study (using criteria adapted from Terwee et al. (2018) and Schellingerhout et al. (2012)).

Method

Review questions:

1. What self-report measures have been used to assess depression within PNC populations?
2. What are the psychometric properties of these measures?
3. Which self-report measures should be considered most valid and reliable for measuring depression in these populations?

Searches

The following databases were searched: PsycINFO, Medline, Scopus, Web of Science, CINAHL and the Cochrane Central Register of Controlled Trials (CENTRAL) between December 2019 and April 2020. The reference lists of relevant systematic reviews identified in this search were also examined to identify further possible papers.

The search strategy included the following terms: "Progressive Neurological Conditions" OR "neurodegen*" OR "motor neuron*" OR "MND" OR "Lou Gehrig*" OR "ALS*" OR "Amyotrophic Lateral Sclerosis" OR "Lewy Bod* OR (muscl* OR muscul*) AND (disease* OR

disorder* OR weaknes*) OR "Huntington*" OR "Multiple Sclerosis" OR "Parkinson*" OR "Multiple System Atrophy" AND the terms "scale" OR "questionnaire" OR "index" OR "measure" OR "assessment" OR "psychometric" AND the keyword "depress*" OR 'major depressive disorder". Although dementia could be classed as a PNC, it was not included as it was beyond the scope of this review.

Inclusion/exclusion criteria

1. Types of studies to be included: published and unpublished empirical studies. Due to resource limitations, studies were excluded if they were not written in English or reported on a measure that is not available in English.
2. Studies featuring psychometric characteristics of self-report measures of depression were included. Studies that included measures that were clinician-administered or relied on information from carers were excluded.
3. Population: to be included the paper needed to feature adults aged 18+ with a progressive neurological condition. Papers were excluded if they did not include a population with a progressive neurological condition.
4. Cognitive status: papers needed to state that they had carried out a cognitive assessment/screen of included participants. Papers that did not indicate an assessment had been carried out were excluded.
5. Functional status: papers needed to state that they had carried out an assessment of a person's motor functioning.

Data extraction

Following identification of studies based on the outlined search strategy, the papers were examined using the inclusion and exclusion criteria. The titles of papers were initially screened, the abstracts of potentially suitable papers were read, prior to retrieving the full-text articles of papers. This process was carried out by the first author.

Data was extracted using standardised forms based on criteria from the COSMIN checklist (Terwee et al., 2018), along with additional standard headings. The COSMIN criteria was selected as it was developed by experts in the development and evaluation of outcome measures to improve selection of outcome measures for both research and clinical practice and thus fit with the aims of this review. Additional headings were included to provide further general information about the included studies and their characteristics. Information on the following was extracted: study reference; measure name; description of the measure; measure (sub)scales; number of items; response options; internal consistency; measurement error; content validity; and construct validity (including structural validity and hypothesis testing), demographic (including age and gender) and clinical characteristics of the study population(s); and overall quality ratings of the study methodology and measurement properties in relation to each of the aforementioned psychometric domains.

Risk of bias assessment

The quality of the included studies was assessed using an amended version of the COSMIN risk of bias checklist for systematic reviews (see Appendix 1). The checklist was revised to

reflect the scope of this review, specifically, sections pertaining to the development of the questionnaire, as all but one study included a generic measure. The checklist was piloted to ensure that it was fit for purpose, prior to use. Quality ratings of a third of the included studies were cross-checked by the second author. A kappa score was calculated in order to assess the level of agreement between reviewers. Discrepancies were resolved by consensus.

Quality assessment

The criteria listed in table 1 (Mokkink et al., 2017; Prinsen et al., 2018; Terwee et al., 2018) were used to assess the measurement properties of the individual measures identified.

Table 1. Good measurement properties

Measurement property	Rating	Criteria
Structural validity	+	**Classical Theory Test:** CFA: CFI or TLI or comparable measure >0.95 OR RMSEA <0.06 OR SRMR <0.08 **Item Response Theory/Rasch:** No violation of unidimensionality: CFI or TLI or comparable measure >0.95 OR RMSEA <0.06 OR SRMR <0.08 *AND*

		no violation of local independence: residual correlations among the items after controlling for the dominant factor < 0.20 OR Q3's < 0.37 *AND* no violation of monotonicity: adequate looking graphs OR item scalability >0.30 *AND* adequate model fit: IRT: $\chi 2$ >0.01 Rasch: infit and outfit mean squares ≥ 0.5 and ≤ 1.5 OR Z- standardized values > -2 and <2
	?	CTT: Not all information for '+' reported IRT/Rasch: Model fit not reported
	-	Criteria for '+' not met
Internal consistency	+	At least low evidence[3] for sufficient structural validity[5] AND Cronbach's alpha(s) ≥ 0.70 for each unidimensional scale or subscale[5]
	?	Criteria for "At least low evidence[3] for sufficient structural validity[5]" not met
	-	At least low evidence[3] for sufficient structural validity[5] AND Cronbach's alpha(s) < 0.70 for each unidimensional scale or subscale
Reliability	+	ICC or weighted Kappa ≥ 0.70

	?	ICC or weighted Kappa not reported
	-	ICC or weighted Kappa < 0.70
Hypotheses testing for construct validity	+	The result is in accordance with the hypothesis[5]
	?	No hypothesis defined (by the review team)
	-	The result is not in accordance with the hypothesis[5]
Concurrent validity	+	Correlation with gold standard ≥ 0.70 OR AUC ≥ 0.70
	?	Not all information for '+' reported
	-	Correlation with gold standard < 0.70 OR AUC < 0.70
Responsiveness	+	The result is in accordance with the hypothesis[5] OR AUC ≥ 0.70
	?	No hypothesis defined (by the review team)
	-	The result is not in accordance with the hypothesis[5] OR AUC < 0.70

AUC = area under the curve, CFA = confirmatory factor analysis, CFI = comparative fit index, CTT = classical test theory, DIF = differential item functioning, ICC = intraclass correlation coefficient, RMSEA: Root Mean Square Error of Approximation, SEM = Standard Error of Measurement, SRMR: Standardized Root Mean Residuals, TLI = Tucker-Lewis index

1 "+" = sufficient, " –" = insufficient, "?" = indeterminate

2 To rate the quality of the summary score, the factor structures should be equal across studies

3 As defined by grading the evidence according to the GRADE approach

4 This evidence may come from different studies

5 The results of all studies should be taken together and it should then be decided if 75% of the results are in accordance with the hypotheses

Following the quality assessment and rating of the individual studies, the findings were pooled, for each identified self-report measure. A version of the GRADE criteria (GRADE, 2013), which was revised by the COSMIN criteria authors to support the use of the COSMIN methodology (Mokkink et al., 2017; Prinsen et al., 2018; Terwee et al., 2018) was used to quality assess the pooled results of the identified studies and aid recommendations on the use of measures, based on the available evidence (see table 2).

Table 2. Modified GRADE approach for grading the quality of evidence

Quality of evidence	Lower if
High	Risk of bias -1 Serious -2 Very serious -3 Extremely serious Inconsistency -1 Serious -2 Very serious Imprecision -1 total n=50-100 -2 total n<50 Indirectness -1 Serious -2 Very serious
Moderate	
Low	
Very Low	

After taking into account factors outlined in table 2 such as consistency of findings reported in the studies identified, quality levels were assigned to each measurement property as

shown in table 3. Where there was only one study reporting on a specific criterion, but the quality of the study was high and there were no major methodological issues, this was classed as a 'moderate' quality study, similarly, if there were only two studies identified with inconsistent findings, this was also classed as 'moderate', see table 3.

Table 3. Quality level criteria

Quality level	Definition
High	We are very confident that the true measurement property lies close to that of the estimate* of the measurement property
Moderate	We are moderately confident in the measurement property estimate: the true measurement property is likely to be close to the estimate of the measurement property, but there is a possibility that it is substantially different
Low	Our confidence in the measurement property estimate is limited: the true measurement property may be substantially different from the estimate of the measurement property
Very low	We have very little confidence in the measurement property estimate: the true measurement property is likely to be substantially different from the estimate of the measurement property

* Estimate of the measurement property refers to the pooled or summarized result of the measurement property.

Face Validity

In addition to the above, the face validity of the identified measures was also assessed using a version of an existing questionnaire, tailored to this review (Cintas et al., 2011). Specifically, three questions were reviewed relating to the clarity of the measure items, whether they should be included and any potential overlap with signs and symptoms of a PNC. These were rated on a four-point scale from strongly disagree to strongly agree, these ratings were then used to class a measure as having 'high', 'moderate' or 'low' face validity. Face validity was included as it can also influence the usability of a measure, despite it being the most subjective form of validity, and would help ensure that the aims of the review are met.

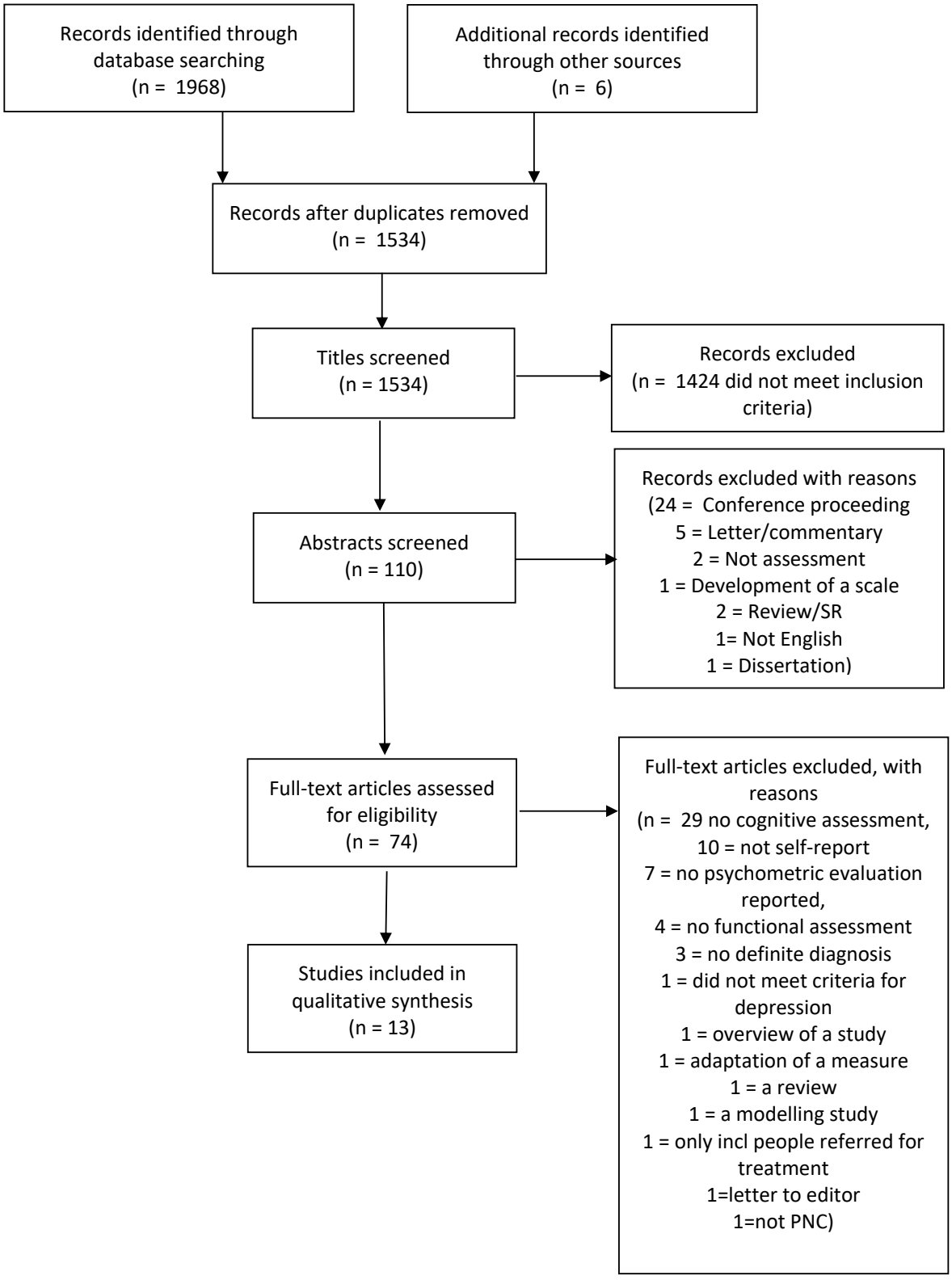
Data Synthesis

Due to the heterogeneity within the papers identified, a narrative synthesis was carried out. The data to be synthesised related to the reliability and validity of the identified measures, to inform their overall usability.

Results

In total, 1968 papers were identified for this review, 13 of which remained following the study selection process, this can be seen in figure 1.

Figure 1. PRISMA Diagram of study selection process (Moher et al., 2009)


Records identified through database searching (n = 1968)
Additional records identified through other sources (n = 6)
Records after duplicates removed (n = 1534)
Titles screened (n = 1534)
Records excluded (n = 1424 did not meet inclusion criteria)
Abstracts screened (n = 110)
Records excluded with reasons (24 = Conference proceeding 5 = Letter/commentary 2 = Not assessment 1 = Development of a scale 2 = Review/SR 1= Not English 1 = Dissertation)
Full-text articles assessed for eligibility (n = 74)
Full-text articles excluded, with reasons (n = 29 no cognitive assessment, 10 = not self-report 7 = no psychometric evaluation reported, 4 = no functional assessment 3 = no definite diagnosis 1 = did not meet criteria for depression 1 = overview of a study 1 = adaptation of a measure 1 = a review 1 = a modelling study 1 = only incl people referred for treatment 1=letter to editor 1=not PNC)
Studies included in qualitative synthesis (n = 13)

Study characteristics

Characteristics for each of the studies can be seen in table 4. Most (11/13; 84.6%) of the identified studies included a population with Parkinson's disease. The remaining studies consisted of people with Multiple Sclerosis (1/13; 7.7%) and Huntington's disease (1/13; 7.7%). The proportion of women included in studies ranged from 1.4% to 70.2%. The mean age of participants ranged from 39.3 (SD 11.2) to 79.2 (SD 7.9).

Six measures were identified, the Geriatric Depression Scale (GDS ; Yesavage et al., 1983), the Beck Depression Inventory (BDI-I/II; Beck et al., 1961, 1996), the Hospital Anxiety and Depression Scale (HADS; Zigmond & Snaith, 1983), the Edinburgh Depression Scale (EDS; Cox et al., 1987) the Brief Edinburgh Scale (BEDS; Lloyd-Williams et al., 2007) and the Depression Screening in Parkinson's disease (DESPAR; Paelecke-Habermann et al., 2009) see table 5 for further details. Various comparators were used by the studies, including DSM-IV criteria for depression (Ertan et al., 2005; Leentjens et al., 2000; Silberman et al., 2006; Tumas et al., 2008; Weintraub et al., 2006, 2007), the Hamilton Depression Scale (Mondolo et al., 2006; Weintraub et al., 2007) and the EuroQol (Rodriguez-Blazquez et al., 2009). It should be noted that one of the included studies used the HADS as a comparator (Massai et al., 2018).

The included studies used various cognitive screens/assessments, including the Mini-Mental State Exam (MMSE; Folstein et al., 1975), Unified Huntington's Disease Rating Scale (UHDRS; Huntington Study Group, 1996), Unified Parkinson's Disease Rating Scale (UPDRS; Fahn et al., 1987), the CAMDEX/CAMCOG (Roth et al., 1986). Mean MMSE scores ranged from 25.7-28.8, indicating that studies did not include participants with identifiable cognitive decline as suggested by a score of 24 or less (Creavin et al., 2016).

Various measures were used to assess participants' motor function. These included the Hoehn and Yahr Scale (H&Y; Hoehn & Yahr, 1967), the UHDRS, the Expanded Disability Status Scale (EDSS; Kurtzke, 1983), and the UPDRS (see table 4). For all of these previously mentioned scales, the higher the score, the greater the impairment.

The way in which studies reported motor function varied, both between and across measures, for instance, some studies using H&Y reported the mean value, whereas some reported the proportion within each category. Of the studies that reported mean H&Y, participants were in early stage PD. Four of the included studies (Leentjens et al., 2000; Rodriguez-Blazquez et al., 2009; Silberman et al., 2006; Storch et al., 2011) included people in the more severe stages of PD. Between 11-19.6% of participants met stage 3 criteria indicating they were mid-stage, 1-17% of participants met stage 4 criteria indicating the disease had progressed to severely disabling, 0.5-1% were classed as being in stage 5, the most advanced stage. While studies included assessments of motor function, unfortunately none appear to take into account how this may influence a person's ability to complete a self-report measure.

Table 4. Summary of included studies

Author & year	Condition	Sample size	% Female	Age (SD)	Country	Cognitive function	Motor function
Baillon (2014)	Parkinson's disease	120	44.9%	74(13.8)	UK	MMSE – Median = 28 (IQR= 2.0)	Hoehn & Yahr Stage 1 & 2 - 93%
Dale (2015)	Huntington's disease	492	55.1%	53.1 (12.1)	Europewide	UHDRS - Total functional capacity - 8.54 (SD = 3.79; range 1-13)	Total motor score – 33.92 (SD=28.83; range 0-95)
Ertan (2005)	Parkinson's disease	109	33%	66.5 (11)	Turkey	MMSE – Mean = 25.7 (SD = 3.0)	Hoehn & Yahr Mean Stage = 2.1 (range 1-5) UPDRS – 35 (SD=19; range 3-96)
Leentjens (2000)	Parkinson's disease	53	41.5%	67 (10.5)	The Netherlands	MMSE - 27.8 (SD = 1.8; range, 23–30)	Hoehn-Yahr Stage 1 – 6%

							Stage 2 – 35% Stage 3 – 11% Stage 4 – 1%
Massai (2018)	Parkinson's disease	74	40.5%	66.9 (9.7)	Italy	MMSE - 29 (27.25; 30)*	Barthel Index – 85 (range 0-100) Parkinson's Disease Questionnaire – 59 (range 0-100)
Mondolo (2006)	Parkinson's disease	46	39%	67.7 (8.2)	Italy	MMSE – 27.8 (SD = 1.5)	Hoehn & Yahr Mean Stage = 2.1 (SD 0.5)
Rodriguez-Blazquez (2009)	Parkinson's disease	387	45.7%	65.9 (11.1)	Spain	SCOPA-Cog – Mean = 23.3 (SD = 7.3; range 2-40)	Hoehn & Yahr Stage 1 – 25.1% Stage 2 –50.4% Stage 3 – 19.3% Stage 4 – 4.7%

							Stage 5 – 0.5%
Sacco (2016)	Multiple Sclerosis	141	70.2%	39.3 (11.2)	Italy	Various	EDSS Mean=2.0 (range 1.0-8.0)
Silberman (2006)	Parkinson's disease	46	41.3%	68.1	Brazil	MMSE (Scores NR) CAMDEX/CAMCOG	Hoehn & Yahr Stage 1 – 21.7% Stage 2 – 19.6% Stage 2.5 – 32.6% Stage 3 – 19.6% Stage 4 – 6.5%
Storch (2011)	Parkinson's disease	215	45%	68 (9)	Germany	MMSE-Scores NR, but all $\geq$24	Hoehn & Yahr Stage 1-1.5 – 17% Stage 2-2.5 –55% Stage 3 – 18% Stage 4 – 17% Stage 5 – 1%

Tumas (2008)	Parkinson's disease	50	48%	63.5 (12.7)	Brazil	UPDRS-Scores NR	Hoehn & Yahr Mean Stage = 2 Shortened UPDRS Motor Score 12.3 (SD = 8.5)
Weintraub (2007)	Parkinson's Disease	226	11.9%	68.6 (4.1)	USA	MMSE – Mean = 27.5 (SD=2.5)	Hoehn & Yahr Mean Stage = 2.35 UPDRS Motor Score = 25
Weintraub (2006)	Parkinson's disease	148	1.4%	72 (8.5)	USA	MMSE – Mean = 27.9 (SD=2.3)	Hoehn & Yahr Mean Stage = 2.3 (SD= 0.6) UPDRS Motor Score = 21.96 (10.7)

MMSE-Mini Mental State Exam, UHDRS-Unified Huntington's Disease Rating Scale, UPDRS-Unified Parkinson's Disease Rating Scale, CAMDEX/CAMCOG-Cambridge Cognitive Examination, NR-Not reported, SD-Standard deviation, IQR-interquartile range

*Median score with 25th and 75th percentiles

Measures identified

The measures identified within the studies also varied, in terms of their content, length and whether they were generic, or condition specific. The characteristics of the individual measures are summarised in table 5.

Table 5. Measures assessed by included studies

Measure	Number of items	Subscales	Sample item	Response options	Known properties in adult populations	Cost?
Beck Depression Inventory (Beck et al., 1961, 1996)	21	None	"I am so sad or unhappy I can't stand it."	4-point scale from 0 (symptom absent) to 3 (severe symptoms)	The BDI-II is positively correlated with the Hamilton Depression Rating Scale (r = 0.71)[a] α = 0.92 for psychiatric outpatients and α = 0.93 for college students[b]	Yes

Brief Edinburgh Depression Scale (Lloyd-Williams et al., 2007)	6	None	"Things have been getting on top of me"	4-point scale	α = 0.78 amongst people with cancer [c] *No further psychometric information available*	Free
Depression Screening in Parkinson's disease (Storch et al., 2011)	15	None	"Last week I felt sad"	4-point scale from 0 (always) to 3 (never)	The DESPAR correlates with the BDI-I (r = 0.78)[d] α = 0.91 in people with Parkinson's [d]	Unknown
Edinburgh Depression Scale (Cox et al., 1987)	10	None	I have blamed myself unnecessarily	4-point scale from 0 (symptom absent) to 3 (severe symptoms)	The EDS correlates with the GHQ (r=0.8)[f].	Free

			when things went wrong		α = 0.88[e] in post-natal women[f]	
Geriatric Depression Scale (Yesavage et al., 1983)	30	None	"Are you basically satisfied with your life?"	Yes/No response options	The GDS positively correlates with the HAM-D (*r*=0.8)[g] α = 0.94 for psychiatric and non-psychiatric populations[g]	Free
Hospital Anxiety and Depression Scale (Zigmond & Snaith, 1983)	14	Anxiety (7-items) Depression (7-items)	"I feel as if I'm slowed down"	4-point scale from 0 (symptom absent) to 3 (severe symptoms)	Correlations between the GHQ and HADS-D were *r*=0.50 and 0.66, and between GHQ	Yes

					and HADS-A *r*=0.50 and 0.68[h.] Mean α =0.83 for HADS-A and 0.82 for HADS-D in cancer and somatic populations[h].	

[a]Beck et al., (1996) [b]Beck et al., (1988)

[c]Lloyd-Williams et al., (2009)

[d]Storch et al., (2011)

[e]Becht et al., (2001) [f]Leonardou et al., (2009)

[g]Yesavage et al., (1982)

[h]Bjelland et al., (2002)

Reliability and validity of measures

Geriatric Depression Scale (GDS)

The GDS was the most well researched measure and was featured within six of the studies (Ertan, et al., 2005; Massai et al., 2018; Mondolo et al., 2006; Tumas et al., 2008; Weintraub et al., 2006; Weintraub et al., 2007). It was used within studies with people with PD. The quality of evidence for the GDS was classed as moderate-high.

Three of the included studies (Ertan et al., 2005; Massai et al., 2018) reported on internal consistency, which ranged from α=0.90 to 0.92. Only one of the included studies (Massai et al., 2018) reported an intraclass correlation coefficient, which was 0.94, indicating good temporal reliability.

Construct validity was reported by three of the included studies (Massai et al., 2018; Mondolo et al., 2006; Tumas et al., 2008). Findings were inconsistent with correlation coefficients ranging from *r*=0.59-0.88. Six of the studies examined criterion validity and included ROC curves, reporting areas under the curve of 0.89-0.95 (see table 6).

Beck Depression Inventory (BDI-I/II)

The BDI-I/II was featured in four of the included studies (Leentjens et al., 2000; Sacco et al., 2016; Silberman et al., 2006, Tumas et al., 2008). It was used within studies with people with PD and MS. The quality of evidence for use of the BDI-I/II ranged from moderate to high, as a result of inconsistent findings or small number of studies addressing a specific aspect.

Two studies (Sacco et al., 2016, Silberman et al., 2006) reported on internal consistency; Cronbach's alphas ranged from 0.36-0.89. Construct validity was examined by two studies (Sacco et al., 2016; Tumas et al., 2008), which reported correlation coefficients ranging from *r*=0.62-0.79. All four of the studies examined criterion validity and included ROC curves, reporting areas under the curve of 0.79-0.92, see table 6.

Hospital Anxiety and Depression Scale (HADS)

The HADS was featured within three of the included studies (Dale et al., 2015, Rodriguz-Blazquez et al., 2009; Mondolo et al., 2006). It was used within studies with people with PD and HD. Evidence provided by these studies was rated as moderate/low to high, as above, due to the small number of studies and inconsistent findings.

One study (Dale et al., 2015) investigated the structural validity of the HADS, reporting a CFI for the two factors of 0.82, which would be classed as poor; this study also suggested that a number of items should be removed, due to potential overlap between symptoms of depression and symptoms of HD. Two studies reported on internal consistency (Dale et al., 2015, Rodriguz-Blazquez et al., 2009), with Cronbach's alphas ranging from 0.67-0.83. Construct validity was examined by two studies (Mondolo et al., 2006; Rodriguz-Blazquez et al., 2009), with associated correlation coefficients of *r*=-0.56 to 0.61. One study reported criterion validity and included a ROC curve, with an area under the curve of 0.98. Only one of the studies examining the use of the HADS reported proposed cut-offs of 10/11 and associated sensitivity and specificity, of 1.00 and 0.95, respectively (Mondolo et al., 2006).

Edinburgh Depression Scale (EDS)/Brief Edinburgh Depression Scale

The EDS and Brief-EDS (Baillon et al., 2014) were examined in one of the included studies, featuring people with PD. Given that the following is based on one study of adequate quality, the quality of evidence was rated as moderate. The study reported construct validity citing correlations of 0.89 (95% CI=0.81–0.97) for the EDS and 0.86 (95% CI 0.77–0.95) for the Brief-EDS.

Depression Screening in Parkinson's Disease

The DESPAR was included in one of the studies (Storch et al., 2011), featuring people with PD. Given that the following is based on one study of adequate quality, the quality of evidence was rated as moderate. This study reported on internal consistency, citing a Cronbach's alpha of 0.91. The study also reported construct validity citing a correlation of *r*=0.92 (95%CI: 0.89–0.96).

Table 6. Study Findings

Measure	Author & Year	Condition	Model fit	Internal consistency	Concurrent validity comparator	Concurrent validity	Sensitivity	Specificity	Area under curve	Cut off points
GDS	Ertan (2005)	Parkinson's disease	NR	α=0.92	SCAN	NR	0.78	0.85	0.89	13/14
	Massai (2018)	Parkinson's disease	NR	α=0.90	HADS	*r*=0.71-0.88	0.87	0.82	0.89	15-16
	Mondolo (2006)	Parkinson's disease	NR	NR	HAM-D	*r*=0.59	1.00	0.76	0.89	10/11
	Tumas (2008)	Parkinson's disease	NR	NR	DSM-IV criteria	*r*=0.62	0.91	0.92	0.94	10-11
	Weintraub (2006)	Parkinson's disease	NR	NR	DSM-IV criteria	*r*=0.92	0.88 0.66	0.85 0.97	0.92	4/5 (screening) 6/7 (diagnostic)

	Weintraub (2007)	Parkinson's disease	NR	NR	DSM-IV criteria	*r*=0.91-0.95	0.85 0.89 0.90	0.84 0.82 0.90	0.91-0.95	4/5 (non-elderly) 4/5 (young-elderly) 5/6 (old-elderly)
BDI-I/II	Sacco (2016)	Multiple Sclerosis	NR	α=0.89	CMDI	*r*=0.79	0.78	0.88	0.91	18.5
	Leentjens (2000)	Parkinson's disease	NR	NR	DSM-IV criteria	*r*=0.86	0.92 0.42	0.59 0.98	0.86	8/9 (screening) 16/17 (diagnostic)
	Silberman (2006)	Parkinson's disease	NR	α=0.36-0.62	DSM-IV criteria	NR	0.67	0.92	0.79	18
	Tumas (2008)	Parkinson's disease	NR	NR	DSM-IV criteria	*r*=0.62	1.00 0.80	0.76 0.95	0.92	17/18 (screening)

										26/27 (diagnostic)
HADS	Dale (2015)	Huntington's disease	CFI 0.82	α=0.67, 0.79	N/A	NR	NR	NR	NR	NR
	Mondolo (2006)	Parkinson's disease	NR	NR	HAM-D	*r*=0.61	1.00	0.76	0.89	10/11
	Rodriguez-Blazquez (2009)	Parkinson's disease	NR	α=0.81, 0.83	EuroQoL	*r*=-0.48, -0.56	NR	NR	NR	NR
EDS/ BEDS	Baillon (2014)	Parkinson's disease	NR	NR	SCAN	NR	NR	NR	0.89/0.86	10/11
DESPAR	Storch (2011)	Parkinson's disease	NR	α=0.91	MINI	*r*=0.92 (95%CI: 0.89–0.96)	0.76	0.77	0.92	29/30

Key: NR-Not reported;

Model fit: CFI >0.95 OR RMSEA <0.06 considered good

Internal consistency: Cronbach's $\alpha \geq 70$ considered acceptable; **Concurrent validity:** Correlation with gold standard ≥ 0.70 OR AUC ≥ 0.70

EDS-Edinburgh Depression Scale, Brief-Edinburgh Depression Scale, HADS-Hospital Anxiety and Depression Scale, GDS-Geriatric Depression Scale, BDI-Beck Depression Inventory, DESPAR-Depression Screening in Parkinson's Disease, SCAN-Schedules for Clinical Assessment in Neuropsychiatry, DSM-IV American Psychiatric Association Diagnostic and Statistical Manual Version IV, HAM-D-Hamilton Depression Rating Scale, MINI-Mini International Neuropsychiatric Interview.

Quality assessment

Quality ratings for each of the studies is shown in table 7. A third of the studies were reviewed by a second reviewer. Cohen's kappa for agreement between the two reviewers was 0.83, suggesting a very good level of agreement (Landis & Koch, 1977). The quality varied across and within studies, such that some aspects of a study could have been rated 'very good', whereas other aspects were rated as 'inadequate'.

Table 7. Psychometric Properties and Associated Ratings of the Identified Measures

Measure	Population validated in	Alpha level	Reliability	Structural validity	Criterion Validity	Convergent Validity	Discriminative Validity	Criterion approach (comparison to a gold standard)	Construct validity	Criterion Validity (comparison between subgroups)
GDS	Parkinson's disease[1]	0.92	VG	N/A	VG	A	D	VG	D	D
	Parkinson's disease[2]	0.90	ICC 0.94	N/A	VG	A	N/A	0.89 (95% CI 0.81–0.98)	0.71 -0.88	N/A
	Parkinson's disease[3]	-	A	N/A	VG	I	VG	0.94	0.62	VG
	Parkinson's disease[4]	-	N/A	N/A	VG	VG	VG	0.92	VG	VG

	Parkinson's disease[5]	-	N/A	N/A	VG	VG	VG	0.91-0.95	VG	VG
	Parkinson's disease[6]	-	N/A	N/A	VG	VG	N/A	0.89	0.59	N/A
BDI-I/II	Multiple Sclerosis[7]	0.89	N/A	N/A	VG	VG	N/A	0.91	0.79	N/A
	Parkinson's disease[8]	-	N/A	N/A	VG	D	N/A	0.86	D	N/A
	Parkinson's disease[9]	0.36-0.62	D	N/A	VG	A	N/A	79.7% (95% CI=63.7%-95.6%)	D	N/A
	Parkinson's disease[3]	-	A	N/A	VG	I	VG	0.92	0.62	VG
HADS	Huntington's disease[10]	0.67, 0.79	D	VG	N/A	N/A	N/A	N/A	N/A	N/A

	Parkinson's disease[7]	-	N/A	N/A	VG	VG	N/A	0.98	0.61	N/A
	Parkinson's disease[11]	0.81, 0.83	N/A	A	N/A	I	D	N/A	-0.48, -0.56	N/A
EDS/BEDS	Parkinson's disease[12]	-	N/A	VG	D	VG	VG	0.89 (95% CI=0.81–0.97)/0.86 (95% CI 0.77–0.95)	D	VG
DESPAR	Parkinson's disease[13]	0.91	N/A	N/A	VG	D	D	0.92 [95%CI: 0.89–0.96]	D	VG

[1]Ertan (2005) [2]Massai (2018) [3]Tumas (2008) [4]Weintraub (2006) [5]Weintraub (2007) [6]Mondolo (2006) [7]Sacco (2016) [8]Leentjens (2000) [9]Silberman (2006) [10]Dale (2015) [11]Rodriguez-Blazquez (2009)

[12]Baillon (2014) [13]Storch (2011)

VG-very good, A-adequate, D-doubtful, I-inadequate, N/A-not applicable

Face validity

In addition to carrying out the analysis of the identified studies using COSMIN criteria, the face validity of the measures was also assessed by the first author, see table 8.

Table 8. Face validity ratings of measures (revised from Cintas, 2011)

Measure	All of the items should be included	All of the items are clearly worded	Items are easily discriminated from symptoms of a PNC	**Overall rating**
GDS	Strongly agree	Strongly agree	Agree	***High***
BDI	Disagree	Agree	Disagree	***Moderate***
HADS	Disagree	Strongly agree	Disagree	***Low/Moderate***
EDS/BEDS	Strongly agree	Strongly agree	Strongly agree	***High***
DESPAR	Strongly agree	Strongly agree	Strongly agree	***High***

Response items for the BDI are quite nuanced and may be difficult for a person with cognitive decline associated with a PNC to differentiate. As well as this, many of the items were considered to overlap with symptoms of a PNC, such as concentration difficulty. Similarly, the HADS was also downgraded due to the overlap between symptoms of a PNC and symptoms of depression, such as 'I feel as if I'm slowed down'. In addition, some of the items on the HADS are similar to each other, which may cause confusion for someone with cognitive decline.

Suitability of measures for PNC

Lastly, the psychometric properties of all of the identified measures were pooled together in order to enable a judgement about whether the measure may be suitable for use with a person with a PNC, this is shown in table 9. Based on this, it would appear that only the GDS has suitable evidence, at the time of writing, to support its use within this population.

Table 9. Pooled psychometric properties of measures

Measure	Number of studies	Overall sample size	Structural validity	Internal consistency	Reliability	Construct validity	Criterion validity	Recommended for use?
GDS	6	1222	NR	Cronbach α = 0.90-0.92 (2)	ICC 0.94 (1)	*r*=0.59-0.88 (3)	AUC=0.89-0.95 (5)	Yes
BDI	4	290	NR	Cronbach α = 0.36-0.89 (2)	NR	*r*=0.62-0.79 (2)	AUC=0.79-0.92 (4)	No
HADS	3	925	CFI 0.82 (1)	Cronbach α = 0.67-0.83 (2)	NR	*r*=-0.48, -0.56 *r*=0.61 (2)	AUC=0.98 (1)	Not in its current form
EDS/BEDS	1	120	NR	NR	NR	*r*=0.86. 0.89 (1)	NR	Further research required

DESPAR	1	215	NR	Cronbach α = 0.91 (1)	NR	*r*=0.92 (1)	NR	Further research required

Numbers in brackets represent number of studies the information is drawn from.

GDS-Geriatric Depression Scale, BDI-Beck Depression Inventory, HADS-Hospital Anxiety and Depression Scale, EDS/BEDS-Edinburgh Depression Scale/Brief Edinburgh Depression Scale, DESPAR-Depression Screening in Parkinson's Disease, NR-Not reported, CFI-Comparative Fit Index, AUC-Area under the curve, ICC-intraclass correlation coefficient.

Key:

- CFI ≥0.95 = good fit
- *r*=0.00-0.19 'very weak', *r*=0.20-0.39 'weak', *r*=0.40-0.59 'moderate', *r*=0.60-0.79 'strong', *r*=0.80-1.00 'very strong' (Evans, 1996).
- α < 0.5 'unacceptable', α = 0.50-0.59 'poor', α = 0.60-0.69 'questionable', α = 0.70-.0.79 'acceptable', α = 0.80-0.89 'good', α = 0.90-1.00 'excellent' (George & Mallery, 2003).
- AUC = diagnostic accuracy of the test, where a value of 0 indicates a perfectly inaccurate test and a value of 1 reflects a perfectly accurate test.

Risk of bias across studies

The DESPAR has not as yet been studied independently of the research team that has developed it, thus independent replication is required of findings from the DESPAR. This would also provide a greater sample from which to determine the utility of the measure.

Some of the measures that were identified were only examined in one study, although the identified studies were of adequate quality it is possible they may not be truly reflective of the suitability of the measure for use within the chosen population.

Sample sizes varied across studies varied from 46 to 569 and it is possible that both the smaller and the larger sample sizes may have influenced the findings of the statistical analyses carried out by authors. Lastly, the proportion of women in the studies varied greatly, from 1.4-70.2%. It is known that the prevalence of depression varies by gender and thus this wide variation, may have also had some bearing on the outcomes of the studies and any recommendations made relating to their use in both research and practice.

Discussion

This systematic review was carried out to summarise the evidence on the validity and reliability of self-report measures of depression for use with people with PNC. Thirteen papers were identified that met the inclusion criteria. This review was carried out in response to treatment guidelines that state the importance of being able to identify and treat depression within these populations, yet do not suggest which measures may be most appropriate. This was felt to be an important area to research given the high levels of depression reported within these populations.

Six measures were identified, the GDS, BDI-I/II, HADS, EDS, BEDS, and DESPAR. The GDS was the most well researched measure identified and had been applied in studies with people with PD. Only one study assessed a population-specific measure, with the remaining addressing the validity and reliability of generic measures. The evidence to support the use of these measures varied. The comparator criterion measures used by the studies varied greatly and indeed one of the studies used comparator measures of which another study was assessing the validity and reliability. Similar findings were reported by an existing review addressing depression rating scales in PD (Torbey et al., 2015), which recommended the use of the GDS. It is interesting to note that while these studies focused on the validity and reliability of a self-report measure, the comparator in a lot of cases was the DSM-IV, which should only be used by a qualified mental health practitioner and thus is based on the judgement of someone other than the person with a PNC.

The BDI-I/II despite including a number of somatic symptoms, was included in a small number of the identified studies. As stated above, the utility of this within a PNC population is questionable for a number of reasons, including the varied response options and reverse scoring of questions. As a result, it is possible that a person with cognitive impairment due to a PNC, may be misclassified and thus may have difficulty accessing appropriate services. As well as this, the BDI-I/II has an associated cost, which may make its use prohibitive in publicly funded healthcare systems. The remaining three questionnaires, the DESPAR and the EDS/BEDS were only examined in a single study each. The idea of using the EDS/BEDS which was developed to identify post-natal depression within a PNC population is interesting. Further research may help shed light on whether the factors included within it can really be

classed as relevant for potentially older populations, experiencing functional and cognitive decline. The use of the DESPAR is very much in its infancy and while it may show promise, due to it being developed specifically for a PNC, it must be highlighted that at the time of writing, it had only been evaluated by the authors of the measure and thus may be subject to bias.

The most frequently explored areas of validity and reliability were internal consistency, construct validity and criterion validity. Only one of the included studies (Dale et al., 2015), which examined the use of the HADS with people with HD examined the structural validity of the included measures, despite the fact that the items included within the measures or their subscales may be responded to differently within this population. Indeed, in their conclusion Dale et al., did suggest the removal of six items, three from each subscale, in order to increase its fitness for use within a PNC population. Certainly the removal of items would make the scale briefer and may also make the questions easier to understand, as the items that remain are more straightforward. It is also likely these changes may make the HADS more usable by other PNC populations. However, the fact remains that the response options change from item to item and thus may potentially cause confusion. Despite this, it is likely that further research is required to support the suggested changes to the scale.

The cut-off scores suggested by authors also varied, potentially as a result of the different comparator measures being employed, which has implications for those wishing to apply these measures either in research or in clinical practice. In particular, the cut-off scores for the GDS varied from 10/11 (Mondolo et al., 2006) in one study to 15/16 in another (Massai et al., 2018), with similar levels of specificity reported by both sets of authors. However, it

should be noted that these studies used different criterion measures, with one reporting 'moderate' and the other 'very strong' correlation coefficients, which may have influenced the cut-off points reported. Similarly, three studies featuring people with PD with similar levels of motor functioning, which used the DSM-IV criteria for depression as a comparator reported different cut-offs and different levels of sensitivity and specificity (Tumas et al., 2008; Weintraub et al., 2006, 2007). It is also interesting to note that one of these studies reported a "moderate" (r=0.62) correlation coefficient as opposed to 'very strong" (r=0.91 and 0.95) coefficients. It is possible that the differences reported may be due to the sample size, which varied from 50 to 226 and the proportion of women included in the studies, which varied from 1.4% (Weintraub et al., 2007) to 48% (Tumas et al., 2008). It is also possible that these differences may be due to different interpretations of the DSM-IV criteria. Despite the differences in findings reported, both the methodology of these studies and the quality of the evidence based on the pooling of studies was considered very good/high.

Only studies that featured a cognitive screen/assessment were included in the review, in an attempt to identify whether the examined self-report measures may be appropriate for use with people with cognitive decline associated with the included conditions. While it could be argued that in the earlier stages of the disease that a generic measure would be equally as appropriate as within the general population, it is once someone progresses that their utility could be questioned. Based on the available literature, it would seem that the GDS may be appropriate for use with people with cognitive impairment. It should also be mentioned that a high number of identified studies were excluded because they did not cognitively screen or assess participants, which suggests that a lot of the research being carried out to examine the reliability and validity of self-report depression measures within these populations is failing

to take into account something that in itself can be very distressing and also may affect a person's ability to complete the measure.

To be included in the review, studies needed to include an assessment of a person's motor function. Authors used various approaches, most often the Hoehn and Yahr scale. However, unfortunately despite recording this information, none of the studies examined the impact of motor difficulties on the outcomes being explored. This appears to be a clear limitation of the work that has been carried out in this area thus far, given that a person's motor functioning could potentially limit their ability to complete a self-report measure, or may indeed influence whether someone experiences depression. It is unfortunate that authors have not chosen to explore this area further as it would likely have implications for use of the measures outlined. Research has been carried out to examine the benefit of oral completion of the GDS, which could potentially mitigate some of the difficulties outlined, however, it would seem that people rate their distress lower when completed orally compared to when they self-complete the measure (Cannon et al., 2002). Another potential adaptation could include electronic versions of the measures, with press button response options which do not require pencil/pen holding, however, it would appear that the research thus far has only examined the use of paper versions of these measures. In light of the Covid-19 pandemic, the ease of which screening can be carried out may be affected, in which case, briefer measures, such as the 15-item GDS, via the telephone may be useful, although potentially more resource intense. However, this would help those involved in the care of someone with a PNC assess for any depression, from a safe distance. Although a person may rate their depression as lower, as suggested above, it is important to be pragmatic when face-to-face appointments are limited.

This review focused exclusively on self-report measures, however, other measures do exist that take into account information from carers, such as the Cornell Scale for Depression in Dementia (Alexopoulos et al., 1988). Similarly, a number of measures were identified that are clinician-rated, such as the Hamilton Rating Scale for depression (Hamilton, 1960) or the Montgomery-Asberg Depression Rating Scale (Montgomery & Asberg, 1979). However, use of these measures have resource implications which may thus influence their usability by untrained members of staff. In addition, it has been suggested that information from carers may be influenced by their own levels of distress associated with their caring responsibility (Chang et al., 2011). In addition, it should also be noted that the CORE-10 measure, which is routinely used within the United Kingdom's National Health Service, was not included in any of the studies, however, this is likely because it was not identified through the use of the selected search terms as it is a global measure of distress, rather than specifically addressing depression. In addition, while the CORE-10 may have been included in some of the grey literature (including clinical reports) initially identified, as this did not meet the review's strict inclusion criteria it was not included.

Implications for clinical practice

The pooling of findings from various PNC was beneficial as it allows decisions to be made on the use of self-report measures within populations, such as those with HD, where limited research has been carried out to explore the validity and reliability of such measures.

One of the barriers to use of certain self-report measures in practice is cost. Both the HADS and BDI-I/II require payment per copy. In comparison, the GDS, EDS and BEDS are free to use and readily downloadable from the internet.

Length of the questionnaires varied from the GDS with 30 items to the Edinburgh Depression Scale which contains 10 items. It may be important to consider length due to the fatigue associated with the included conditions. Three of the included studies (Tumas et al., 2008; Weintraub et al., 2006, 2007) used the 15-item version of the GDS, while there is an even briefer version (4-items; D'Ath et al., 1994), at the time of writing, this had not been investigated within this population. Furthermore, while the GDS was originally developed for use with older adults, research suggests it may also be usable with younger adults with PNC (Weintraub et al., 2007). An existing review highlighted the utility of the GDS for people with PD (Torbey et al. 2015), the findings of this review would suggest that it may also be a reliable and valid measure for use with people with PNC in general. However, this existing review does not describe whether included studies took into account participants cognitive and motor functioning and the potential impact of these on the use of the identified measures. In addition, the approach used within the review does not clearly delineate how, or if, studies were assessed for quality. It is also interesting to note that this review suggests that the BDI and the HADS may be appropriate screening measures, which the authors of this study disagree with, it is possible that the authors' conclusions were as a result of the methodological limitations mentioned. The review described herein, overcomes these potential limitations. A similar review (Patrick & Connick, 2019) addressed the utility of the PHQ-9 within a population with MS, while the PHQ-9 may have utility within a PNC

population, none of the studies that met the strict inclusion criteria for this review featured the PHQ-9.

To date, guidelines relating to the care and management of people with PNC do not advise what measures should be used to screen for depression within the population. It is suggested that it may be worthwhile to do so, given the varying levels of evidence supporting the use of measures, as outlined herein. Based on the analysis of the identified measures, at the time of writing, it would seem that only the GDS may be fit for use within a PNC population, based on the quality of the evidence available, the identified psychometric properties, its apparent face validity and the fact that it is free to use. While there are various versions of the GDS available, it is suggested that the 15-item should be used to alleviate any burden associated with its application. As well as this, the associated sensitivities and specificities appear better for the cut-off points of the shorter version. Lastly, the authors (Weintraub et al., 2006; 2007) provide cut-off points for different age groups and also for screening compared to assessment, which may assist the practical application of the measure and interpretation by those who regularly work with people with PNC. It is suggested that the GDS15 could be used by non-mental health workers, such as PD specialist nurses, as a screening tool during regular appointments with people with PNC to help identify whether further referral and support is required. However, this would only be appropriate within a system where there is access to psychological/psychiatric services. It may also be beneficial to be used as an assessment tool by secondary care mental health professionals as an objective measure of depression, as part of a wider assessment. Use of the GDS in such a manner may also help overcome the lack of research at present, supporting its ability to address change over time.

Limitations

One of the limitations of this review was the difficulty in drawing sound conclusions and implications for practice, based on the amount of variation within the identified studies. Specifically, comparator measures varied and associated cut-off scores also varied potentially making it difficult to draw definitive conclusions as to what the best self-report measure to use might be. However, it should be mentioned that this was due to the literature available, as opposed to the methodology employed by this review.

Given the limited number of studies available, it is possible that the pooling for quality ratings may have resulted in aspects of studies being downgraded, which would have had implications for the recommendations outlined herein.

It was also difficult to summarise the evidence on some of the measures (e.g. EDS, DESPAR) due to the limited amount of research that had been carried out. While it could be argued that these studies should have been removed from the review, they were included to show that there are additional measures that can be used with people with PNC, which show promise and should be explored further.

Recommendations to improve measurement science

Studies focusing on people with PNC should take into account both cognitive and motor function. This should go beyond merely classifying participants based on the stage of disease progression. Study authors should explore the impact that greater level of impairment has

on a person's ability to complete measures, given what is known about the link between greater impairment and greater mental health difficulties.

Study authors should not include a blanket exclusion of people based on the severity of their condition, as this limits what can be learned about the utility of self-report measures with people with greater impairment. While it may be more labour intense, it would be worthwhile to consider assessing how able individual people may be to report on their mood and their situation and based on this choose whether to include them within a study.

It is important that research is carried out to further what is known about the utility of condition-specific measures. Only one, the DESPAR, fulfilled inclusion criteria, although the author is aware of an ALS-specific measure (Hammer et al., 2008). Researchers should explore the utility of these measures, taking into account both cognitive and motor impairments as it is possible that they may have greater face validity than some of the measures outlined herein.

Based on the varying levels of reporting within the identified studies, a minimum set of reporting criteria is proposed, guided by the COSMIN quality assessment guidelines. Studies focusing on validity and reliability should report on the internal consistency, construct validity and criterion validity as outlined herein. Ideally, the comparator measures used should be the gold standard and information pertaining to its use within the chosen population should be provided in order to justify its use to the naïve reader. Studies should also examine the test-retest reliability of the measures, which would help draw conclusions about the stability of the measures across time and could further support their use within the PNC population.

Conclusion

People with PNC are more likely than the general population to experience depression. Guidelines state that it is important to assess and treat depression within these populations. This systematic review identified a number of self-report measures of depression that have been examined for use within PNC populations. Based on the evidence available, it would appear that the GDS may be the most appropriate measure as it has the most supporting evidence, comes in briefer forms and is free to use. In addition, the simple yes/no response options and the high face validity make this a suitable option for people with PNC. In particular, for those using the 15-item version, it would appear that a cut-off score of 4/5 has optimum sensitivity and specificity (Weintraub et al., 2006, 2007), however, further research may be required to identify an ideal cut-off for the 30-item version due to the disparities reported in the literature.

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Appendix 1. Modified COSMIN Quality assessment form

Study Authors and Year **Rater: _____**

Structural validity

Does the scale consist of effect indicators, i.e. is it based on a reflective model? yes / no

Does the study concern unidimensionality or structural validity? [2]

	Very Good	**Adequate**	**Doubtful**	**Inadequate**	**N/A**
Statistical methods					
Was exploratory or confirmatory factor analysis performed?	Confirmatory factor analysis performed	Exploratory factor analysis performed		No exploratory or confirmatory factor analysis performed	Not applicable
For Rasch: does the chosen model fit to the research question?	Chosen model fits well to the research question	Assumable that the chosen model fits well to the research question	Doubtful if the chosen model fits well to the research question	Chosen model does not fit to the research question	Not applicable
Was the sample size included in the analysis adequate?	FA: 7 times the number of items and ≥100	FA: at least 5 times the number of items and ≥100; OR at least 6 times number of items but <100	FA: 5 times the number of items but <100	Rasch/1PL models: < 50 subjects	Not applicable

	Rasch/1PL models: ≥ 200 subjects	Rasch/1PL models: 100-199 subjects	2PL parametric IRT models OR Mokken scale analysis: 250-499 subjects	2PL parametric IRT models OR Mokken scale analysis: < 250 subjects	
	2PL parametric IRT models OR Mokken scale analysis: ≥ 1000 subjects	2PL parametric IRT models OR Mokken scale analysis: 500-999 subjects	FA: < 5 times the number of items		
Were there any other important flaws in the design or statistical methods of the study?	No other important methodological flaws		Other minor methodological flaws (e.g. rotation method not described)	Other important methodological flaws (e.g. inappropriate rotation method)	

Internal consistency

Does the scale consist of effect indicators, i.e. is it based on a reflective model? [1] yes / no

	Very Good	**Adequate**	**Doubtful**	**Inadequate**	**N/A**
Design requirements					
Was an internal consistency statistic calculated for each unidimensional scale or subscale separately?	Internal consistency statistic calculated for each unidimensional scale or subscale		Unclear whether scale or sub scale is unidimensional	Internal consistency statistic NOT calculated for each unidimensional scale or sub scale	
Statistical methods					

For continuous scores: Was Cronbach's alpha or omega calculated?	Cronbach's alpha, or Omega calculated		Only item-total correlations calculated	No Cronbach's alpha and no item-total correlations calculated	Not applicable
For dichotomous scores: Was Cronbach's alpha or KR- 20 calculated?	Cronbach's alpha or KR-20 calculated		Only item-total correlations calculated	No Cronbach's alpha or KR-20 and no item-total correlations calculated	Not applicable
For IRT-based scores: Was standard error of the theta (SE (θ)) or reliability coefficient of estimated latent trait value (index of (subject or item) separation) calculated?	SE(θ) or reliability coefficient calculated			SE(θ) or reliability coefficient NOT calculated	Not applicable
Other					
Were there any other important flaws in the design or statistical methods of the study?	No other important methodological flaws		Other minor methodological flaws	Other important methodological flaws	
Outcome:					

Reliability

	Very Good	**Adequate**	**Doubtful**	**Inadequate**	**N/A**
Design requirements					
Were the test conditions similar for the measurements? e.g. type of administration, environment, instructions *Statistical methods*	Test conditions were similar (evidence provided)	Assumable that test conditions were similar	Unclear if test conditions were similar	Test conditions were NOT similar	Not applicable – only if study not addressing reliability
For continuous scores: Was an intraclass correlation coefficient (ICC) calculated?	ICC calculated and model or formula of the ICC is described	ICC calculated but model or formula of the ICC not described or not optimal. Pearson or	Pearson or Spearman correlation coefficient calculated	No ICC or Pearson or Spearman correlations calculated	Not applicable

		Spearman correlation coefficient calculated with evidence provided that no systematic change has occurred	WITHOUT evidence provided that no systematic change has occurred or WITH evidence that systematic change has occurred		
For dichotomous/nominal/ordinal scores: Was kappa calculated?	Kappa calculated			No kappa calculated	Not applicable
For ordinal scores: Was a weighted kappa calculated?	Weighted Kappa calculated		Unweighted Kappa calculated or not described		Not applicable
For ordinal scores: Was the weighting scheme described? e.g. linear, quadratic	Weighting scheme described	Weighting scheme NOT described			Not applicable
Other					
Were there any other important flaws in the design or statistical methods of the study?	No other important methodological flaws		Other minor methodological flaws	Other important methodological flaws	Not applicable
Outcome:					

Measurement error

	Very Good	**Adequate**	**Doubtful**	**Inadequate**	**N/A**
Design requirements					

Were the test conditions similar for the measurements? (e.g. type of administration, environment, instructions)	Test conditions were similar (evidence provided)	Assumable that test conditions were similar	Unclear if test conditions were similar	Test conditions were NOT similar	
Statistical methods					
For continuous scores: Was the Standard Error of Measurement (SEM), Smallest Detectable Change (SDC) or Limits of Agreement (LoA) calculated?	SEM, SDC, or LoA calculated	Possible to calculate LoA from the data presented		SEM calculated based on Cronbach's alpha, or on SD from another population	
For dichotomous/nominal/ordinal scores: Was the percentage (positive and negative) agreement calculated?	% positive and negative agreement calculated	% agreement calculated		% agreement not calculated	
Other					
Were there any other important flaws in the design or statistical methods of the study?	No other important methodological flaws		Other minor methodological flaws	Other important methodological flaws	

Criterion Validity

	Very Good	**Adequate**	**Doubtful**	**Inadequate**	**N/A**
Statistical methods					
For continuous scores: Were correlations, or the area under the receiver operating curve calculated?	Correlations or AUC calculated			Correlations or Not AUC calculated	NOT applicable
For dichotomous scores: Were sensitivity and specificity determined?	Sensitivity and specificity calculated			Sensitivity and Not specificity calculated	NOT applicable

Other					
Were there any other important flaws in the design or statistical methods of the study?	No other important methodological flaws		Other minor methodological flaws	Other important methodological flaws	
Outcome:					

Hypotheses testing for construct validity

Comparison with other outcome measurement instruments (convergent validity)

	Very Good	**Adequate**	**Doubtful**	**Inadequate**	**N/A**
Design requirements					
Is it clear what the comparator instrument(s) measure(s)?	Constructs measured by the comparator instrument(s) is clear				Constructs measured by the comparator instrument(s) is not clear
Were the measurement properties of the comparator instrument(s) sufficient?	Sufficient measurement properties of the comparator instrument(s) in a population similar to the study population	Sufficient measurement properties of the comparator instrument(s) but not sure if these apply to the study population	Some information on measurement properties of the comparator instrument(s) in any study population	No information on the measurement properties of the comparator instrument(s), OR evidence for insufficient measurement properties of the comparator instrument(s)	
Statistical methods					

Was the statistical method appropriate for the hypotheses to be tested?	Statistical method was appropriate	Assumable that statistical method was appropriate	Statistical method applied NOT optimal	Statistical method applied NOT appropriate	
Other					
Were there any other important flaws in the design or statistical methods of the study?	No other important methodological flaws		Other minor methodological flaws (e.g. only data presented on a comparison with an instrument that measures another construct)	Other important methodological flaws	
Outcome:					

Comparison between subgroups (discriminative or known-groups validity)

	Very Good	**Adequate**	**Doubtful**	**Inadequate**	**N/A**
Design requirements					
Was an adequate description provided of important characteristics of the subgroups?	Adequate description of the important characteristics of the subgroups	Adequate description of most of the important characteristics of the subgroups	Poor of no description of the important characteristics of the subgroups		
Statistical methods					
Was the statistical method appropriate for the hypotheses to be tested?	Statistical method was appropriate	Assumable that statistical method was appropriate	Statistical method applied NOT optimal	Statistical method applied NOT appropriate	
Other					
Were there any other important flaws in the design or statistical methods of the study?	No other important methodological flaws		Other minor methodological flaws (e.g. only data presented on a	Other important methodological flaws	

			comparison with an instrument that measures another construct)		
Outcome:					

Responsiveness

Criterion approach (i.e. comparison to a gold standard)

	Very Good	**Adequate**	**Doubtful**	**Inadequate**	**N/A**
Statistical methods					
For continuous scores: Were correlations between change scores, or the area under the Receiver Operator Curve (ROC) curve calculated?	Correlations or Area under the ROC Curve (AUC) calculated			Correlations or AUC NOT calculated	Not applicable
For dichotomous scales: Were sensitivity and specificity (changed versus not changed) determined?	Sensitivity and specificity calculated			Sensitivity and Not specificity calculated	NOT applicable
Other					
Were there any other important flaws in the design or statistical methods of the study?	No other important methodological flaws		Other minor methodological flaws	Other important methodological flaws	
Outcome:					

Construct approach (i.e. hypotheses testing; comparison with other outcome measurement instruments)

	Very Good	Adequate	Doubtful	Inadequate	N/A
Design requirements					
Is it clear what the comparator instrument(s) measure(s)?	Constructs measured by the comparator instrument(s) is clear			Constructs measured by the comparator instrument(s) is not clear	
Were the measurement properties of the comparator instrument(s) sufficient?	Sufficient measurement properties of the comparator instrument(s) in a population similar to the study population	Sufficient measurement properties of the comparator instrument(s) but not sure if these apply to the study population	Some information on measurement properties of the comparator instrument(s) in any study population	NO information on the measurement properties of the comparator instrument(s) OR evidence of poor quality of comparator instrument(s)	
Statistical methods					
Was the statistical method appropriate for the hypotheses to be tested?	Statistical method was appropriate	Assumable that statistical method was appropriate	Statistical method applied NOT optimal	Statistical method applied NOT appropriate	
Were there any other important flaws in the design or statistical methods of the study?	No other important methodological flaws		Other minor methodological flaws	Other important methodological flaws	
Outcome:					

Construct approach: (i.e. hypotheses testing: comparison between subgroups)

	Very Good	Adequate	Doubtful	Inadequate	N/A
Design requirements					

Was an adequate description provided of important characteristics of the subgroups?	Adequate description of the important characteristics of the subgroups	Adequate description of most of the important characteristics of the subgroups	Poor or no description of the important characteristics of the subgroups		
Statistical methods					
Was the statistical method appropriate for the hypotheses to be tested?	Statistical method was appropriate	Assumable that statistical method was appropriate	Statistical method applied NOT optimal	Statistical method applied NOT appropriate	
Other					
Were there any other important flaws in the design or statistical methods of the study?	No other important methodological flaws		Other minor methodological flaws	Other important methodological flaws	
Outcome:					

Assessment Submission Guidelines - https://uk.sagepub.com/en-gb/eur/journal/assessment#submission-guidelines (accessed 15/04/20)

The editor invites high quality manuscripts covering a broad range of topics and techniques in the area of psychological assessment. These may include empirical studies of assessment of personality, psychopathology, cognitive functions or behavior, articles dealing with general methodological or psychometric topics relevant to assessment, or comprehensive literature reviews in any of these areas. This journal encourages submissions evaluating a) new assessment methodologies and techniques for both researchers and practitioners, b) how assessment methods and research informs understanding of major issues in clinical psychology such as the structure, classification, and mechanisms of psychopathology, and c) multi-method assessment research and the integration of assessment methods in research and practice. Additionally, the journal encourages submissions introducing useful, novel, and non-redundant instruments or demonstrating how existing instruments have applicability in new research or applied contexts. All submissions should provide strong rationales for their efforts and articulate important implications for assessment science and/or practice

Research participants may represent both clinical and nonclinical populations. Manuscripts should include how sample size has been determined, all data exclusions, all manipulations, and all measures in the study.

In general, regular articles should not exceed 30 pages of text, excluding Title Page, Abstract, Tables, Figures, Footnotes and Reference list.

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Registered Reports:

Assessment now offers registered reports (RRs) as an alternative to the regular articles format. The primary distinction between these two manuscript types is that the regular articles are submitted to the journal after data collection and analyses are completed, whereas the RR format reverses this ordering such that manuscripts are submitted prior to data analysis (and often to data collection). Prospective authors of a RR submit a Stage 1 manuscript, which reviews the literature that motivates the study and specifies the methods to address the question. This Stage 1 manuscript then goes through the peer-review process. This RR review process is similar to that for regular articles and reviewers and the editorial team will suggest revisions and recommend acceptance or rejection. Ultimately, if the journal editor determines that the Stage 1 manuscript is suitable for publication, then it is offered *In Principle Acceptance* (IPA). A manuscript offered IPA is an agreement between the journal and the author indicating that assuming the authors carry out the research precisely has they have specified and draws a conclusion based on the evidence, then *Assessment* will publish the work. Following the IPA, the authors carry out the research and then prepare a Stage 2 manuscript that is submitted to the journal. Of course, the authors retain the right to withdraw the manuscript at any point, before or after IPA and these will be recorded by the journal in a publicly available section called Withdrawn Registrations. After resubmission, the Stage 2 manuscript is appraised by the editor and either accepted formally, or sent out to the original reviewers. In this case, the Stage 2 manuscript is only evaluated for the degree to which it faithfully followed the originally planned analyses, drew warranted conclusions, as well as for a review of any exploratory analyses that may have followed.

Guidelines for Registered Reports at Assessment:

As with all registered reports (RRs), those submitted to Assessment should include a complete introduction and methods section. In general, the approach to preparing these sections aims to be consistent with the guidelines offered by the Center for Open Science, but priority is given to these local guidelines where they may differ. The authors should provide all the relevant information that will facilitate peer-reviews and an editorial decision before the data have been collected (or analyzed, if that method is chosen). Given that the focus of this journal is on the development, validation, and interpretation of instruments, some additional recommendations are offered for preparing RRs for submission to Assessment. Here we discriminate between three broad classes of RRs that can be considered at Assessment.

1. The first broad class of RRs are studies that seek to examine the psychometric properties, or construct validation, of *existing instruments*. This can include any number of examinations, such as temporal consistency, factor structure, measurement invariance, predictive validity, or diagnostic accuracy.

2. The second class of RRs are for evaluations that seek to *modify an existing instrument*, such as by creating an abbreviated or revised version of a scale.

3. The third and final class of RRs are for projects that aim to *develop a novel instrument*. This latter class of RRs present a unique and novel extension of the RR process and so authors are encouraged to consult with the Editor-In-Chief in advance of submitting such a manuscript.

Introduction:

The introduction section for all RRs should include a complete review of the relevant literature. For studies examining the properties of an existing instrument, this literature review should introduce the current empirical state of the literature for the focal instrument, as well as the degree to which these properties are known about other instruments of the same or similar constructs. This should pay particular attention to the relevant findings as well as the types of samples utilized to date. The authors should make the clear case for the limitations of this existing literature and what motivates the proposed study. It is worth noting here a series of recommendations offered by Dr. Samuel in his incoming editorial (see Samuel, 2019) in this regard, including the fact that simply demonstrating that something has not been done, does not mean it should be done. This is particularly true for tests of measurement invariance across demographic variables. Recall that for RRs, the authors should be able to make the case that the proposed research will yield relevant conclusions regardless of the findings. In line with best practices for RRs, authors should note that the introduction section is "locked" following the IPA and can only be altered with respect to correcting factual or typographic errors, or meaningful updates to the literature that occurred in the interim.

Method:

Authors should provide a full description of the proposed sampling method as well as the expected characteristics of the acquired sample, based on the proposed procedures that is written in the future tense. This should include inclusion or exclusion criteria, including any pre-screen testing as well as how invalid or incomplete responders will be identified and excluded. This should also include the rationale for utilizing the sample/population and how likely the results are to generalize to the assessment question of interest. The choice of sample size should be informed, where possible, by an *a priori* power analysis based on the best available estimated effect size, which in many cases will be the *lowest* meaningful estimate. A priori power should be above 0.8 for all proposed hypothesis tests. If the goal of the study is to estimate an effect size rather than test a hypothesis, then the authors should provide the best estimate available for that effect. For more complex models statistical models (e.g., factor analysis) a justification for the sample size should be provided. This could be a formal power analysis using simulation methods or justification from methodological literature for adequate power and estimation of the model (see MacCallum, Browne, & Sugawara, 2006). For Bayesian approaches, please consult the OSF guidelines as well as Schönbrodt & Wagenmakers (2016).

The method section should include a complete list of all instruments to be administered, their ordering, as well as the method of administering (e.g., computerized vs. paper and pencil) and scoring the scales (e.g., sum, mean, IRT). If any experimental manipulations are planned, those should be provided in sufficient detail to permit repetition. In short, the method section should provide all the details necessary for an independent researcher to repeat the study.

The proposed analysis pipeline can be included in either a statistical analyses sub-section of the methods, or as a prospective results section. If the latter is chosen, authors should write this section using placeholders for the statistical tests (e.g., "the CFI for model A was .XXX"), such that actual values can be substituted following data analysis. The analysis plan should include all data processing steps, the precise nature of planned analyses, including any covariates to be used and the approach to correcting for multiple comparisons. Ideally, all analysis scripts should be written beforehand and submitted with the Stage 1 report. Further, the use of simulated data to prepare Tables and Figures is highly encouraged. For analytic steps that are contingent upon

results of initial analyses – this will be particularly true for instrument revision and development, please see below – the authors should specify the decision rules that will be used to determine how the results inform subsequent steps and support the rationale for those approaches. Of course, authors are free to conduct any number of analyses beyond those specified in the RR, but those would be included in a separate section of the results, labeled "exploratory analyses." Finally, the method section should specify a timeline by which the study will be completed. Extensions to this deadline for submission of the Stage 2 report are negotiable with the Editor-in-Chief.

Special Considerations for Instrument Development and Revision:

Scale development is an inherently iterative process that includes a large number of decision points, recursive and dependent aspects, and typically multiple data collections that all serve the broader purpose of construct validation (Cronbach and Meehl, 1955). As such, the most appropriate approach to RRs may entail pre-registering a set of decision rules or standard operating procedures that seek to outline aspirational properties of the measure, as well as plans for how competing properties will be prioritized. For example, scale developers may seek to select indicators that correlate highly, but not too highly, with each other, while also balancing the need to cover the breadth of the latent construct. Thus, RR authors may specify a range of inter-indicator correlations that will be prioritized (e.g., values below $r = .60$, but above $r = .20$), while also recognizing that this lower threshold might need to be relaxed to $r = .15$ if low base-rate indicators are necessary to maximize test information between theta of -4.0 and 4.0. The values mentioned here are *not* suggestions, but rather examplars of the type of language and priorities that might be considered. Ultimately, the field may settle on a set of considerations to be specified in a Registered Report of a new instrument, as well as possibly recommendations for the specific properties. Rather than attempting to specify those at this point in time, or wait for them to be developed, the approach at Assessment is to encourage this work and learn from the process. Therefore, we encourage RR authors to consult seminal works on scale construction and construct validation (e.g., Clark & Watson, 1995) to consider the relevant steps that should pre-specified. In general, we encourage the authors to adopt the approach that is most sensible for their instrument. In some cases this might all be anticipated and specified in the Stage 1 manuscript, but Assessment is also open to the practice of incremental registrations that are resubmitted following preliminary data collection.

A critical consideration for RRs that seek to build a novel instrument, is that it is imperative to first demonstrate the need for a new instrument. This necessarily entails an introduction that reviews the most relevant existing instruments measuring the construct, as well as those that measure related or overlapping constructs. The key point here is to outline why an additional measure is needed and how the proposed instrument will fit into the existing literature. Importantly, this *does not* suggest that additional or complementary measures of existing constructs are unnecessary or unwelcome. Quite the contrary. Authors should, however, make clear that the other measures exist and make a compelling case that their conceptualization, operationalization, or measurement approach is a meaningful addition to the field.

Overarching Guidelines and Expectations:

1. Ethics/Institutional Review Board approval for the proposed research is expected to be secured prior to the submission of an RR to Assessment. There may well be changes to the protocol suggested during the Stage 1 review that will need to be vetted as with the IRB/Ethics board, however, existing approval ensures that the research can be conducted as it is proposed. If there are extenuating circumstances that complicate this in a given situation, the prospective authors are encouraged to contact the editor.
2. Similarly, the resources to complete the proposed research are expected to be secured before the Stage 1 submission. As above, this ensures that the resources are in place to carry out the research as it has been proposed. This should include both equipment/facilities as well as funds available for human subjects payments. If there are cases when suggestions during the Stage 1 review may conflict with funding stipulations those can be arbitrated during the Stage 1 review process.

3. Authors of RRs are expected to provide all data, code, and materials publicly available, as a general rule. There will be times when certain materials (e.g., copyrighted instruments) cannot be posted as well as situations where datasets cannot be shared due to human subjects protections or other considerations. In such cases, authors are encouraged to discuss these with the editor as soon as possible to work toward a resolution. The guiding principle is one of openness and transparency so exceptions will require justification.
4. At the point of Stage 1 in-principle acceptance, authors are required to formally register their protocol in a recognized repository, either publicly or under temporary embargo until submission of the Stage 2 manuscript. The Stage 2 manuscript, when submitted, must then include a link to the registered protocol. Stage 1 protocols can be quickly and easily registered at the dedicated Registered Reports registration portal at http://osf.io/rr/

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Chapter 3 – Empirical Paper

Title: An examination of the relationship between psychological flexibility and loneliness in older adults.

Authors: Deirdre Holly[1, 2], Fionnuala Edgar[1], David Gillanders[2]

Affiliation: [1]Dept. of Psychological Services & Research, NHS Dumfries & Galloway [2]School of Health and Social Science, University of Edinburgh

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Abstract

Background: Loneliness can have a detrimental impact on a person's health and well-being. Older adults may be at increased risk of loneliness due to various life changes. Research suggests a person's attachment style alongside interpersonal behaviour may influence loneliness. However, it is unclear how these factors relate to each other and subsequent impact on older adults' mental health. Research suggests potential interactions between attachment anxiety, interpersonal processes and experiential avoidance. This study sought to explore these interactions within the older adult population and in particular, to explore the role of psychological flexibility.

Method: Using a cross-sectional approach, participants completed standardised questionnaires addressing loneliness, anxiety and depression, quality of life, attachment anxiety, interpersonal behaviour and psychological flexibility. Regression analysis was used to identify whether loneliness, interpersonal difficulties and psychological flexibility account for variance in anxiety, depression and quality of life in older adults. Conditional process analysis was used to explore whether psychological flexibility moderates the relationship between attachment anxiety and the outcome variables via the mediators of interpersonal style and loneliness.

Results: Regression analysis showed that loneliness, interpersonal difficulties, attachment anxiety and psychological flexibility were significant predictors of anxiety, depression and quality of life. Simple mediation analysis showed that there was a direct relationship between attachment anxiety and anxiety. Using conditional process analysis, psychological flexibility significantly moderated the relationships between attachment anxiety and the outcome variables. Psychological flexibility moderated the relationships between attachment anxiety and depression and quality of life when psychological flexibility was at mean or high levels, whereas the opposite was found for the relationship between attachment anxiety and anxiety.

Conclusion: The findings suggest that psychological flexibility may be a clear treatment target when working with older adults, as this may help protect against the development of mental health difficulties.

Highlights:

- Predictor and mediator / moderator variables accounted for a substantial amount of observed variance in the dependent variables.
- Attachment anxiety was associated with anxiety.
- Attachment anxiety had an indirect effect on depression and quality of life via loneliness and interpersonal behaviour.
- Psychological flexibility was a significant moderator.

Keywords: Psychological flexibility, older adults, loneliness, attachment, interpersonal difficulties

Introduction

Loneliness

Older adults (OA) may be at increased risk of loneliness due to the many changes associated with this time of life. Loneliness can be described as a subjective, unpleasant and distressing phenomenon resulting from a discrepancy between an individual's desired and achieved levels of social relations (Perlman & Peplau, 1982). Research suggests that within the OA population, defined as those aged 60 and over, approximately 40% may experience loneliness (Perissinotto, et al., 2012). Potential predictors of loneliness include low self-efficacy and self-esteem, low life satisfaction, negative past events and depression (Cohen-Mansfield et al., 2016) all of which can influence a person's ability to form connections with others and the subsequent quality of those connections. As well as loneliness being the result of a number of psychological factors, it can also result in negative outcomes, such as having a detrimental impact on quality of life (QoL). Furthermore, research suggests that if a person scores above a threshold for loneliness, they are 3.74 times more likely to experience psychological distress 2.78 times more likely to be depressed, 1.21 times more likely to experience generalised anxiety disorder and 1.31 times more likely to have suicidal ideation (Beutel et al., 2017; Richard et al., 2017).

Poor mental health among the OA population can be as a result of life-long difficulties, new onset due to factors associated with older adulthood (e.g. retirement, bereavement), or secondary to physical health conditions (e.g. stroke, cancer). Research suggests that approximately 15% of community-dwelling OA may have clinically significant depressive symptoms (Blazer, 2003), as well as this, older women may be more likely to have increased risk of current depression and higher risk of depression and anxiety (Kiely et al., 2019), all of which may affect a person's QoL. The factors that may lead to the onset of psychological difficulties within this population are multifarious and can include factors such as lack of social connection or more deep-seated psychological factors such as difficulty forming relationships.

At the time of writing, loneliness was a public health concern, especially amongst the OA population and was supported by initiatives such as the 'Campaign to End Loneliness'

(https://www.campaigntoendloneliness.org), which was part-funded by National Lottery Funding. Within Scotland, the 'Reshaping Care for Older People 2011-2021' report (Scottish Government, 2013), resulted in additional funds focusing on preventative and community-based services, which subsequently resulted in additional funding for Older Adult Psychology Services to address loneliness within this population. However, despite this, there is evidence to suggest that those aged 65-74 may in fact report the highest average levels of personal well-being (Office of National Statistics, 2016).

Attachment styles

The relationships people form with others and the approaches taken to do so, may have implications for the development of psychological difficulties, especially amongst people who score higher on measures of attachment hostility or anxiety. Much of the research on attachment styles has looked at the extension of attachment theory to adult romantic relationships (Hazan & Shaver, 1987). Attachment anxiety, characterised by a fear of rejection by others, or anxious preoccupation about attachment-related issues, may lead someone to downplay their interests in other people, who unaware of this fear, may thus be less likely to forge a relationship with them, romantic, or otherwise (Vorauer et al., 2003). Conversely, attachment hostility is characterised by an expectation that others will be hostile which may result in the person acting dominant and aggressive in their relationships with others, in response to these expectations. Within the OA population, attachment style can have important implications for how people relate to others, especially given the many changes that come with this period of life, such as the death of close others, as well as the birth of grandchildren, suggesting a change in adult attachment figures during this period (Doherty & Feeney, 2004). In terms of attachment anxiety, which may be of particular relevance to loneliness and the development of psychological difficulties (Gerhart et al., 2014), evidence suggests it may decrease, increase or remain stable, depending on a person's experiences (Van Assche et al., 2013). Despite this, research suggests that attachment anxiety in OA may have a negative impact on self-reported well-being and thus may have a deleterious impact on a person's mental health, however, it has been indicated that social support may moderate this relationship (Van Assche et al., 2013).

Interpersonal processes

Building on the discussion of the potential utility of exploring the relationship between attachment anxiety and psychological difficulties within this population, interpersonal theory may be beneficial for explaining the behaviours that may occur as a result of attachment problems. These are learned behaviours of poor relating, poor relationship maintenance or repair (Barkum et al., 1996). The interpersonal circumplex, which is key to this theory, suggests that interpersonal difficulties may in fact be learned behaviours which fall on two intersecting dimensions, namely cold versus warmth and dominance versus submission. Interpersonal difficulties may arise should someone demonstrate excessive amounts of dominance, coldness, or submission which may result in them struggling to form meaningful relationships with others. In particular, one of these difficulties may be social avoidance which may prevent the person from reaping the benefits of social contact with others and lead to them becoming lonely. In addition, coldness associated with attachment hostility may result in the person pushing others away thus preventing them from connecting with others.

Psychological Flexibility

Psychological flexibility (PF) is a transdiagnostic concept, which underpins Acceptance and Commitment Therapy (ACT) and can be described as the ability to "recognize and adapt to various situational demands; shift mindsets or behavioral repertoires when these strategies compromise personal or social functioning; maintain balance among important life domains; and be aware, open, and committed to behaviors that are congruent with deeply held values" (Kahsdan & Rottenberg, 2010). PF consists of six core processes, namely acceptance, cognitive defusion, being present, self as context, values and committed action, which can be used to develop intervention techniques and strategies.

Limited research has been carried out examining the relationship between PF and attachment style, however, it has been suggested that there may be a negative relationship between these two factors (Salande et al., 2017). Research suggests that PF may moderate the relationship between stress and physical health, mental health and well-being within the general population (Gloster et al., 2017); of note, one of the factors that was explored within this research was low perceived social support. Furthermore, PF has been shown to predict significant variation in psychological distress and QoL (McAteer & Gillanders, 2019). PF and engaged living may also potentially mediate the role between gratitude and loneliness in

adults aged 40 and over (Frinking et al., 2019). In addition, a negative relationship between PF and loneliness has also been suggested (Frinking et al., 2019). This suggests that PF may be useful for protecting against the ill effects of loneliness, as outlined above and more generally, promoting recovery and positive mental health by enabling someone to behave effectively in line with what is important to them, even when experiencing difficulties (Slade, 2010).

Living in accordance with one's values is associated with reduced psychological distress and greater QoL (Trindade et al., 2016). Furthermore, those who are engaged in valued activities experience higher levels of positive affect and lower levels of negative affect (Froh et al., 2010), which may be associated with reduced loneliness (Ditcheva et al., 2018). In further support of this relationship, research suggests lack of meaning; which could be understood as being disconnected from one's values and not engaging in committed actions, is associated with loneliness (Tam & Chan, 2019).

As well as the factors outlined above, it is possible that people who experience loneliness may feel overwhelmed by others due to activation of social comparison, vulnerability to rejection or feeling smothered and may thus avoid social contact to avoid the thoughts and feelings that accompany being around other people. It is via this experiential avoidance that a person may develop interpersonal problems, which may influence their ability to form meaningful relationships with others (Gerhart et al., 2014), particularly for those with an anxious attachment style or those with a history of finding relationships difficult. As well as this, it has been suggested that those who struggle to regulate their emotions may experience greater loneliness as a result of experiential avoidance (Shi et al., 2016). Indeed, theories of loneliness suggest it may be associated with aversive feelings that someone may wish to avoid, which may thus make any potential social interaction appear threatening (Ditcheva et al., 2018). As well as this, avoidance behaviours may have a negative impact on a person's goals, due to interpersonal problems (Holtforth et al., 2006) and may be associated with depression and anger (Gerhart et al., 2013). Moreover, an increase in experiential avoidance may result in an inability to achieve one's valued actions and result in psychological inflexibility (Gerhart et al., 2014). Given that psychological flexibility is a modifiable treatment

target, it makes sense to explore its relationship with loneliness and associated psychological outcomes.

From the research outlined above, it can be said that there may be a number of factors that can influence the development of psychological difficulties within the OA population. It is clear that a person's attachment style plays a key role, alongside interpersonal behaviour and loneliness and that together, these can have a detrimental impact on one's health, both physical and mental. It is also clear that psychological difficulties may be less likely to hinder someone's ability to act in accordance with their values when PF is high. However, it is less clear how these factors relate to each other and subsequent impact on OA mental health. A recent study (Gerhart et al., 2014) provided some provisional evidence to support potential interactions between attachment anxiety, interpersonal processes and experiential avoidance, it is proposed that this may be usefully used to inform research to explore the factors that influence loneliness, mental health and QoL within an OA population. This study will further add to the findings of Gerhart's work by exploring these emerging relationships within an OA population. This study will also broaden out the ACT component and explore PF as a whole, as well as identifying the impact that the factors explored have on anxiety, depression and QoL and thus potentially making findings more relevant to clinical practice. In keeping with Gerhart's work, this study will focus on attachment anxiety rather than attachment as a whole, as the purpose of this study is to identify factors related to loneliness and thus focusing on secure attachment was deemed less appropriate.

The aim of this study was to examine relationships between loneliness, anxiety, depression and QoL, and to examine distal factors (attachment anxiety) and proximal factors (interpersonal behaviours) that could influence or mediate these relationships. In addition, the study investigated whether Psychological Flexibility would moderate these direct and indirect relationships

The objectives were to identify whether:

1. Attachment anxiety is associated with QoL, anxiety and depression in OA.
2. Loneliness and interpersonal difficulties mediate the relationship between attachment anxiety, depression, anxiety and QoL.

3. The impact of loneliness and interpersonal difficulties on anxiety, depression and QoL is moderated by Psychological Flexibility.

Methodology

Design

This was a cross-sectional study. Participants completed a questionnaire, either online or paper-based (Appendix 3). The questionnaire included questions relating to demographic information, as well as standardised self-report questionnaires addressing loneliness, attachment anxiety, interpersonal difficulties, PF, anxiety and depression, and QoL. The online questionnaire was hosted on JISC Online Surveys.

Sample size

Power calculations carried out a priori estimated that a sample size of 117 participants was needed in order to detect a medium effect size using a linear regression with 13 predictors at an alpha level of 0.05 ($p < 0.5$) and a power of 0.80 (Green, 1991). For simple mediation, it is recommended that 77 participants are sufficient to detect medium-sized indirect effects (Fritz & Mackinnon, 2007), therefore, powering this for a regression, will be likely to have sufficient power for the planned analysis.

The choice of a medium effect size in the sample size calculation is based on research using moderated mediation (Gerhart et al., 2014). However, as the calculations using Gerhart's work resulted in large effect sizes, a more conservative medium effect size was chosen, as this work sampled OA as opposed to university students and some aspects were less well researched in this population and thus there was less evidence available to support using a sample size based on an estimate of a large effect size.

Participants

To be included, participants needed to be aged 60 or over, living in the community, able to read and write English and free from cognitive deficits, based on self-assessed criterion.

Measures

Demographics

Participants were requested to provide information on their gender, relationship status, living status, employment status and whether they attended any community groups.

Comprehensive assessment of Acceptance and Commitment Therapy processes (CompACT; Francis et al., 2016)

This is a 23-item measure of PF consisting of three sub-scales: openness to experience, behavioural awareness and valued action. Cronbach's alpha for the CompACT total is 0.91 and for the sub-scales it ranges from α=0.87-0.90. It has good convergent validity when compared to other established ACT process measures (*r*=0.79), similarly, it has large positive correlations with the DASS-21, a measure of symptoms of depression, anxiety, and stress ($r =$ 0.57-0.65), indicating good concurrent validity.

Inventory of Interpersonal Problems (IIP-32; Horowitz et al., 1988)

The IIP-32 is a 32-item measure of distress related to interpersonal processes, which map onto the octants of the Interpersonal Circumplex. The scale consists of eight sub-scales: assertive, sociable, supportive, dependent, caring, aggressive, involved and open. Cronbach's alpha for the IIP-32 is 0.86 and for the individual subscales is α=0.72-0.86. It has moderate convergent validity when compared to a measure of psychological functioning (*r*=0.58*;* Le Coco et al., 2018). It also has large positive correlations when compared to the longer IIP-64 (*r*=0.94-0.96; Barkham et al, 1996) indicating good convergent validity.

Relationship Awareness Scale-Relational Anxiety sub-scale (RAS; Snell, 1998)

The relational anxiety sub-scale of the RAS consists of nine items. This sub-scale addresses the extent to which someone experiences anxiety and discomfort in close relationships, in particular, as a result of attachment anxiety. Cronbach's alpha for the scale is 0.88, indicating good internal consistency. It has moderate convergent validity (*r*=0.53; Snell, 2002) when compared to established measures of social anxiety. A single subscale was chosen to reduce potential burden on OA participants.

UCLA Loneliness Scale-8 item (ULS-8; Hays & DiMatteo, 1987)

The UCLA Loneliness Scale, eight-item version is a measure of loneliness, based on the longer 20-item UCLA Loneliness scale. The content of this scale reflects perceived loneliness, based

on the difference between desired and actual social contact, with higher scores indicating greater loneliness. In terms of the reliability and validity of the measure, findings suggest it has good internal consistency, with a Cronbach's alpha of 0.84. It has good convergent validity when compared to the longer 20-item UCLA loneliness scale (*r*=0.92; Goossens et al., 2014) and also when compared with a single item "I feel lonely" (*r*=0.71; Xu et al., 2018).

Hospital Anxiety & Depression Scale (HADS; Zigmond & Snaith, 1983)

The HADS is a 14-item measure for symptoms of anxiety and depression, which focuses on non-somatic indicators of anxiety and depression to allow for the identification of such difficulties in physically ill populations. Cronbach's alphas for the individual subscales are α=0.68-0.93 for the anxiety subscale and α=0.67-0.90 for the depression subscale (Bjelland et al., 2002) suggesting that the measure has good internal consistency. It has large positive correlations when compared to other measures of anxiety (*r*=0.50-0.81) and depression (*r*=0.50-0.81), indicating good convergent validity. When compared to the PHQ-9, the HADS has a large positive correlation (*r*=0.72; Stafford et al., 2007), indicating good concurrent validity.

Older People's Quality of Life questionnaire-brief (OPQoL; Bowling et al., 2013)

The OPQoL-brief is a 13-item questionnaire developed to address factors associated with QoL, specifically among OA. Cronbach's alpha for the measure is α=0.86, indicating good internal consistency. It has large positive correlations when compared to other measures of QoL (*r*=0.64-0.66; Bowling & Stenner, 2011) indicating good concurrent validity. It has moderate-high convergent validity when compared to factors hypothesized to influence QoL (*r*=-0.22 to -0.56; Bowling & Stenner, 2011)

Recruitment

Participants were recruited through a convenience sampling approach. Local third sector groups, some of which work with people who are socially isolated, such as the Food Train and Men's Sheds distributed the participant information leaflet (Appendix 2) and questionnaire to their service users. The questionnaire link was also tweeted to professional networks, such as the Division of Clinical Psychology and British Psychological Society, as well as independently run groups for OA, such as Contact the Elderly and the Women's Institute.

Analysis

The analysis was carried out using IBM SPSS Statistics for Macintosh, version 24.0 (2016, IBM Corp). The PROCESS (version 3.4) syntax (Hayes, 2017) was used to enable the conditional process analyses. Prior to carrying out the analyses, total scores on the predictor variables were created.

The data were checked for the assumptions of parametric data based on Field (2005). The data was also checked to identify any missing data.

Descriptive and comparative analysis were carried out to provide information about the sample.

T-Tests were carried out on the demographic information, to identify whether there were any significant differences between groups in relation to the independent or dependent variables, indicating the need to control for specific factors in the subsequent regression analyses. The demographic information examined included gender, relationship status, living arrangements, employment status and attendance at community groups. As no significant differences were found, none of these demographic factors were controlled for in subsequent analyses.

Pearson's correlation coefficient was used to identify which factors correlate highly with each other, effect sizes were interpreted based on Cohen (1992). The findings from this were used to inform subsequent regression analysis.

Forced entry multiple linear regression analysis was used to develop models of the factors that statistically predict anxiety, depression and QoL within the OA population. No specific factors were controlled for as t-tests indicated no significant differences based on demographic factors examined. Model validity was assessed by examining the difference between R^2 and the adjusted R^2 to assess any shrinkage or loss of predictive power (Field, 2005). Each model was tested for outliers by examining Mahlanobis distance. P-P plots and histograms were examined to test for normality of residuals, heteroscedasticity and non-

linearity. Final models were tested using the Durbin-Watson test to confirm that the data met the assumption of independent errors (Field, 2005).

A number of simple mediation analyses were carried out using PROCESS Model 4 to help identify which of the variables mediate the relationship between attachment anxiety and anxiety, depression and QoL. Thereafter, conditional process analysis was carried out using PF as a moderator and loneliness and interpersonal processes as mediators. The completely standardised effect was used to interpret the analysis, as this was viewed to be more comparable than the partially standardised effect (Hayes, 2017).

Ethical approval

This study was granted ethical approval by South Central - Berkshire Research Ethics Committee (Ref: 18/SC/0599). Research management approval was provided by the University of Edinburgh. Local management approval was provided by NHS Dumfries & Galloway (18/DGY/029), see Appendix 4-6.

Results

Assumptions of parametric data

Tests for normality of distribution were carried out by inspection of histograms and P-P plots and by employing the Kolmorgorov- Smirnoff test. In addition, Levene's test of homogeneity of variance was also carried out. A number of variables were negatively skewed. Prior to carrying out the analysis, 5% of the data was winsorised, to account for negatively skewed data as recommended by Field (2005). Bootstrapping was also used in the regression analysis to overcome the potential influence of the skewed data, as recommended by Hayes (2017).

Missing data

Data was checked prior to carrying out the analysis, by carrying out frequencies tests on all of the variables. One participant did not complete one question; the rest of their responses were checked to estimate whether the missing value would have skewed the data. No other data was missing and therefore did not need to be addressed prior to data analysis.

Sample characteristics

In total, 117 OA were recruited. Sixty-four percent (75/117) of participants were female. Most participants were married/cohabiting (75/117; 64.1%). Three-quarters (91/117) stated that they have children. Approximately one-quarter (33/117; 28.2%) lived alone. Fifty-five percent (65/117) attended community groups, in addition, 41% (48/117) were currently employed. The full details of the demographics of the sample can be seen in table 1, an overview of the measures used can be seen in table 2.

Table 1. Profile of sample demographics

Characteristic	**Current sample N**	**%**
Gender		
Female	75	64.1
Male	42	35.9
Relationship status		
Married/co-habiting	75	64.1
Widowed	16	13.7
Divorced/separated	14	12.0
Single	10	8.5
Other	1	0.9
Living situation		
Husband/wife/partner	73	62.4
Children/step-children	12	10.3
Mother/father	2	1.7
Other family members	2	1.7
Grand child/ren	1	0.9
Friend	1	0.9
I live alone	33	28.2
Has children	91	77.8
Does not have children	26	22.2

Currently employed	48	41.0
Currently unemployed	69	59.0
Attends community groups	65	55.6
Does not attend community groups	51	43.6

The sample included in this study was compared to normative data, as outlined in table 2. It would appear that this sample was less likely to experience anxiety or depression. The mean levels of attachment anxiety and loneliness were broadly similar. The included sample reported higher levels of interpersonal difficulties and lower levels of psychological flexibility, compared to the comparison groups.

Table 2. Descriptive statistics for dependent and independent variables with comparative data

						Comparative Data	
Variable	**Range**	**Min**	**Max**	**Mean**	**SD**	**Mean**	**SD**
IIP-32	0-160	33	116	67.5	19.5	52.5[a]	7.9 [a]
RAS	0-36	0	36	12.3	11.3	13.1[b]	8.8 [b]
ULS-8	0-24	1	22	11.2	5.3	12.8[c]	3.5 [c]
OPQoL	0-65	22	65	54.3	8.5	53.9[d]	6.7 [d]
HADS-A	0-21	0	20	6.9	4.6	13.7[e]	3.2[e]
HADS-D	0-21	0	18	5.1	4.2	7.4[e]	4.1[e]
CompACT	0-138	42	122	86.7	18.3	91.5[f]	18.8[f]

IIP-32 Inventory of Interpresonal Problems-32; RAS-Relational Anxiety Scale, ULS-8 UCLA Loneliess Scale 8-item; OPQoL- Older People's Quality of Life Scale, HADS Hospital Anxiety and Depression Scale, CompACT - Comprehensive assessment of Acceptance and Commitment Therapy processes

[a]Lo Coco et al (2018) [b]Riggio et al (2011) [c]Satici et al (2016) [d]Kaambwa et al (2015) [e]Ball et al (2015) [f]McAteer & Gillanders (2019)

Correlations

Bivariate correlations were conducted to identify the strength of the relationships between the predictor and outcome variables (see table 3). All of the variables were significantly correlated at the $p \leq 0.001$ level. Attachment anxiety had large positive correlations with anxiety (r=0.56) and depression (r=0.54) and a medium negative correlation with QoL (r=-0.48).

Table 3. Correlation matrix showing predictor and outcome variables

	1	2	3	4	5	6	7
1. HADS-A	1						
2. HADS-D	0.71*	1					
3. OPQoL	-0.61*	-0.77*	1				
4. IIP-32	0.58*	0.54*	-0.52*	1			
5. RAS	0.56*	0.54*	-0.48*	0.78*	1		
6. UCL-8	0.50*	0.51*	-0.55*	0.56*	0.50*	1	
7. CompACT	-0.54*	-0.59*	0.55*	-0.51*	-0.49*	-0.45*	1

*$p \leq 0.05$

Regression

Multiple regression analysis was conducted to identify the predictors of anxiety, depression and QoL, each of the following analyses included interpersonal difficulties, loneliness, PF and attachment anxiety as predictors. Bootstrapping was used to overcome the potential influence of the skewed data, as recommended by Hayes (2017).

Prediction of anxiety

The final model predicted 43% of the variance (Adj R^2= 0.43). This was significant [$F(4,112)=23.57$, $p<0.001$]. Loneliness (UCL-8; β=0.192, $p<0.05$) and PF (CompACT; β=-0.291, $p \leq 0.001$) were significant predictors, see table 4.

Table 4. Regression table of prediction of anxiety

Variable	β	t	p-value	R^2	Adjusted R^2
				0.457	0.438

CompACT	-0.291	-3.466	0.001*
UCL-8	0.192	2.213	0.029*
IIP-32	0.211	1.783	0.077
RAS	0.140	1.236	0.219

*p≤0.05

Prediction of depression

The final model predicted 45% of the variance (Adj R^2= 0.45). This was significant [F(4,112)=24.39, p<0.001]. Loneliness (UCL-8; β=0.2, p<0.05) and PF (CompACT; β=-0.356, p≤0.001) were significant predictors, see table 5.

Table 5. Regression table of prediction of depression

Variable	β	t	p-value	R^2	Adjusted R^2
				0.466	0.446
CompACT	-0.356	-4.270	<0.001*		
UCL-8	0.200	2.323	0.022*		
RAS	0.193	1.722	0.088		
IIP-32	0.093	0.795	0.428		

*p≤0.05

Prediction of quality of life

The final model predicted 44% of the variance (Adj R^2= 0.44). This was significant [F(4,112)=23.77, p<0.001]. Loneliness (UCL-8; β= -0.360, p<0.001) and PF (CompACT; β=0.263, p<0.05) were significant predictors, see table 6.

Table 6. Regression table of prediction of QoL

Variable	β	t	p-value	R^2	Adjusted R^2
				0.459	0.440
UCL-8	-0.360	-4.154	≤0.001*		
CompACT	0.263	3.137	0.002*		
IIP-32	-0.147	-1.245	0.216		

RAS	-0.060	-0.534	0.595

*p≤0.05

Simple mediation

PROCESS Model 4 was used to test the hypothesis that PF, loneliness and interpersonal difficulties mediate the relationship between attachment anxiety and anxiety, depression and QoL. Despite not being an independent predictor, attachment anxiety was used in these analyses to examine whether it may have an indirect effect on the outcome variables, based on the significant correlations shown in table 3. Direct and indirect effects were tested, the indirect effect of attachment anxiety on the outcome (Y) variables was tested using a percentile bootstrap estimation approach with 10000 samples (Shrout & Bolger, 2002), implemented with the PROCESS Macro Version 3 (Hayes, 2017).

Anxiety

Attachment anxiety had a direct effect on anxiety (β=1.37, SE=0.11, p<0.001), this relationship remained significant though was attenuated when controlling for the mediators (β=0.20, SE=0.03, p<0.001). Approximately 33% of the variance (Adj R^2= 0.33) was accounted for by the predictors. These results indicated the indirect coefficient was significant (β=0.39, SE=0.11, 95% C.I.=0.18, 0.59), this can be seen in Figure 1.

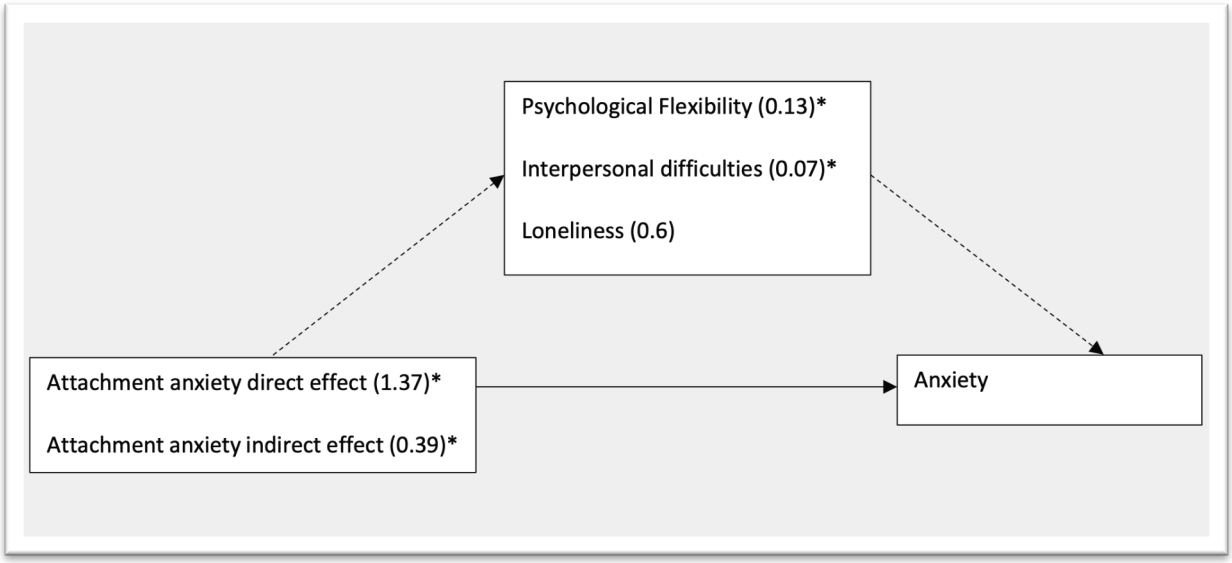

Figure 1. Graphical representation of mediation of relationship between attachment anxiety and anxiety

Key: ——► Direct effect ·····► Indirect effect - - - - - ► Moderated effect

*=p≤0.05

Numbers represent standardised β coefficients

Depression

This mediation was repeated using depression as Y. Attachment anxiety did not have a direct effect on depression (β=0.07, SE=0.04, *p*=0.09), however, when controlling for the mediators, this relationship became significant (β=0.20, SE=0.03, *p*<0.001). Approximately 29% of the variance (Adj R^2=0.29) was accounted for by the predictors. These results indicated the indirect coefficient was significant (β=0.35, SE=0.12, 95% C.I.=0.14, 0.59), this can be seen in Figure 2.

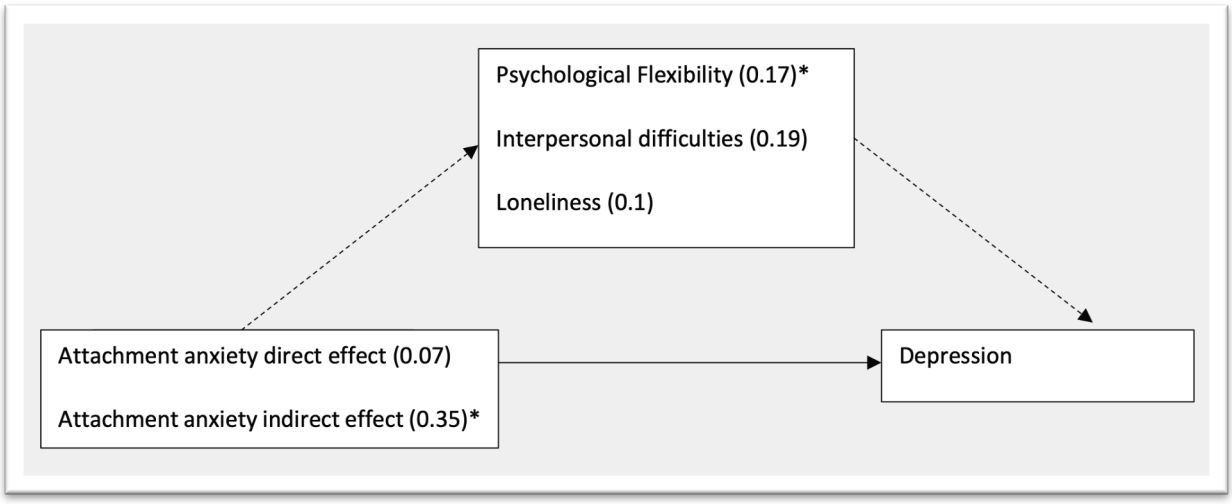

Figure 2. Graphical representation of mediation of relationship between attachment anxiety and depression

Key: ——► Direct effect ·····► Indirect effect - - - - - ► Moderated effect

*=p≤0.05

Numbers represent standardised β coefficients

Quality of Life

This mediation was repeated using QoL as Y. Attachment anxiety did not have a direct effect on QoL (β=-0.05, SE=0.09, *p*=0.62), however, when controlling for the mediators, this relationship became significant (β=-0.36, SE=0.06, *p*<0.001). Approximately 23% of the variance (Adj R^2= 0.23) was accounted for by the predictors. These results indicated the indirect coefficient was significant (β=-0.42, SE=0.09, 95% C.I.=-0.61, -0.25), this can be seen in Figure 3.

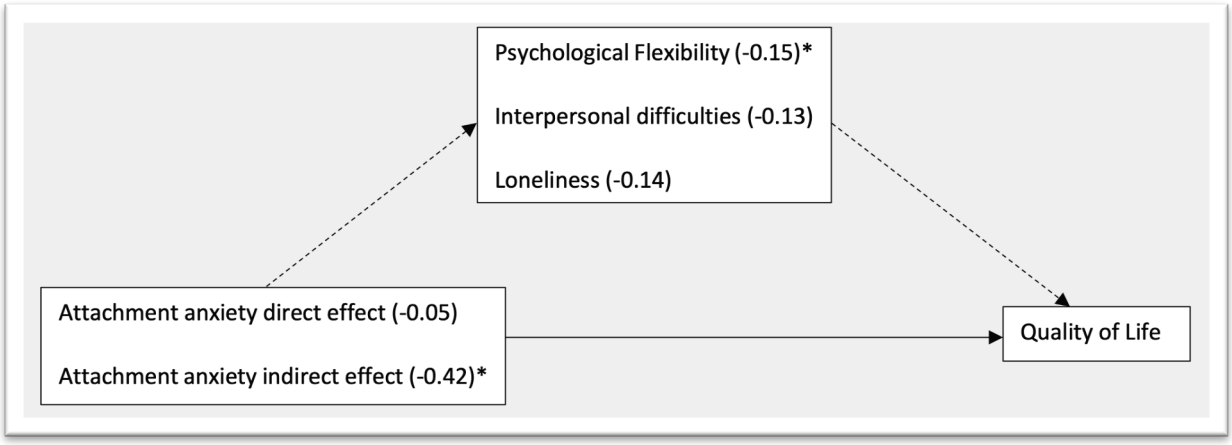

Figure 3. Graphical representation of mediation of relationship between attachment anxiety and QoL

Key: ——► Direct effect ·····► Indirect effect - - - - - ► Moderated effect

*=p≤0.05

Numbers represent standardised β coefficients

Conditional Process Analysis

The outlined correlations and regressions helped address objective 1, the simple mediation analyses suggested a relationship between attachment anxiety and the outcome variables, mediated by loneliness and PF and partially addressed objective 2. Conditional process analysis, using PROCESS model 92 was used to 1. add to the results of the mediation analysis by examining the influence that PF has on the relationship between attachment anxiety and the predictor and outcome variables and 2. identify whether different levels of PF influence these relationships in different ways.

The full model that was tested, using anxiety as an example, is shown in figure 4. To avoid repetition, only the specific findings relating to the moderation will be outlined in the text below.

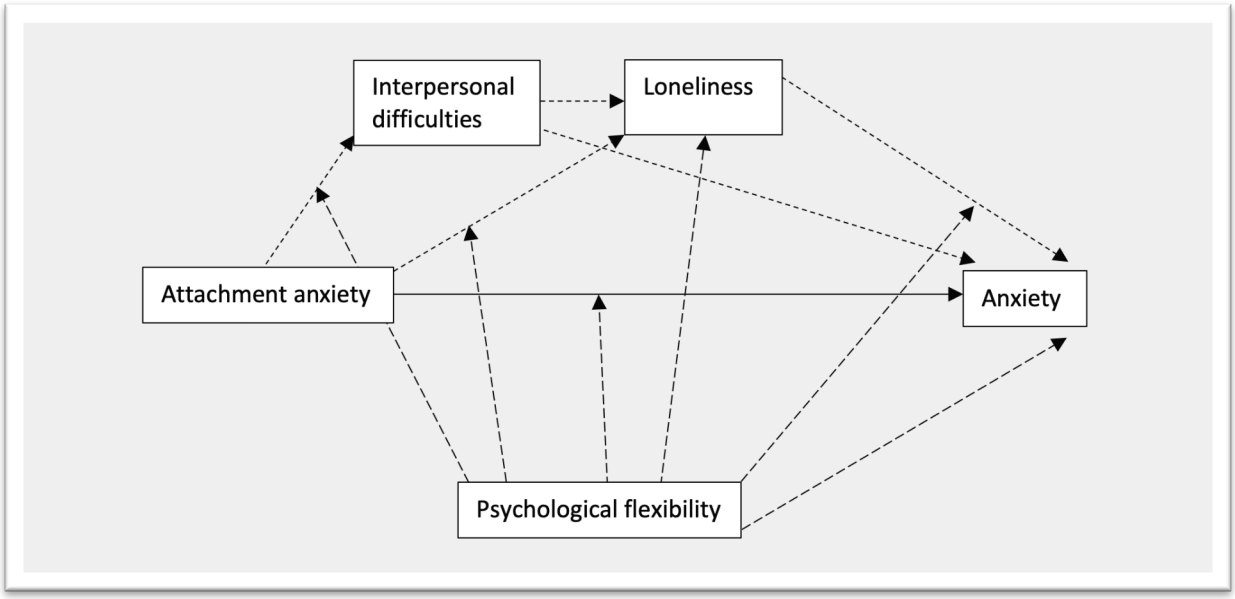

Figure 4. Graphical representation of model 92 tested with predicted relationships using anxiety as an example

Key: ——► Direct effect ·····► Indirect effect - - - - - ► Moderated effect

The model indicated that 52% of the variance was explained by the main effects and interaction effects (R^2=0.52, F(7, 109)=16.84, p<0.001). When PF was low (-1 SD) or at mean levels, interpersonal difficulties became a significant mediator of the relationship between attachment anxiety and anxiety. When PF was high (+1 SD) attachment anxiety had a significant direct effect on anxiety, which does not fit with the specified hypothesis, this can be seen in Figure 5.

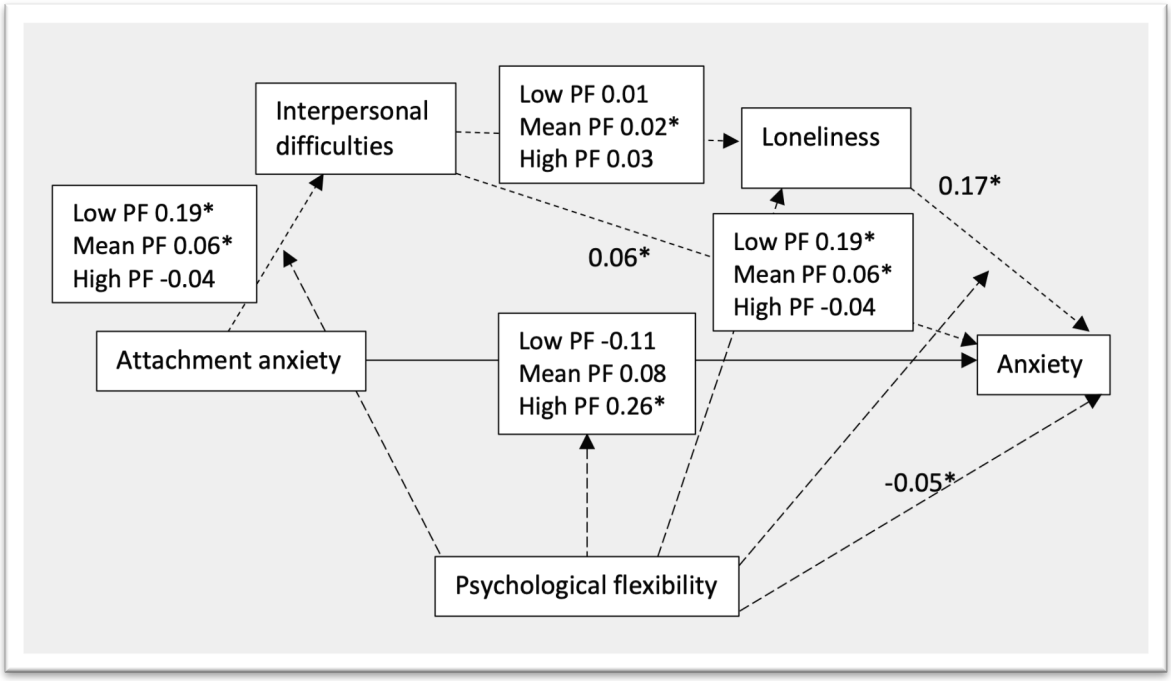

Figure 5. Graphical representation of conditional process analysis of relationship between attachment anxiety and anxiety

Key: ——► Direct effect ·····► Indirect effect - - - - - ► Moderated effect

*=p≤0.05

Numbers represent standardised β coefficients

The analysis was repeated, using depression as the outcome variable, this model accounted for 51% of the variance, (R^2=0.51, F(7,109)=16.44, p<0.001). When PF was at mean or high levels, the indirect pathway between attachment anxiety and depression became statistically significant, this can seen in Figure 6. Thus at low levels of PF, the predictors are merely associated with attachment anxiety, whereas at mean or high levels the relationship becomes more nuanced.

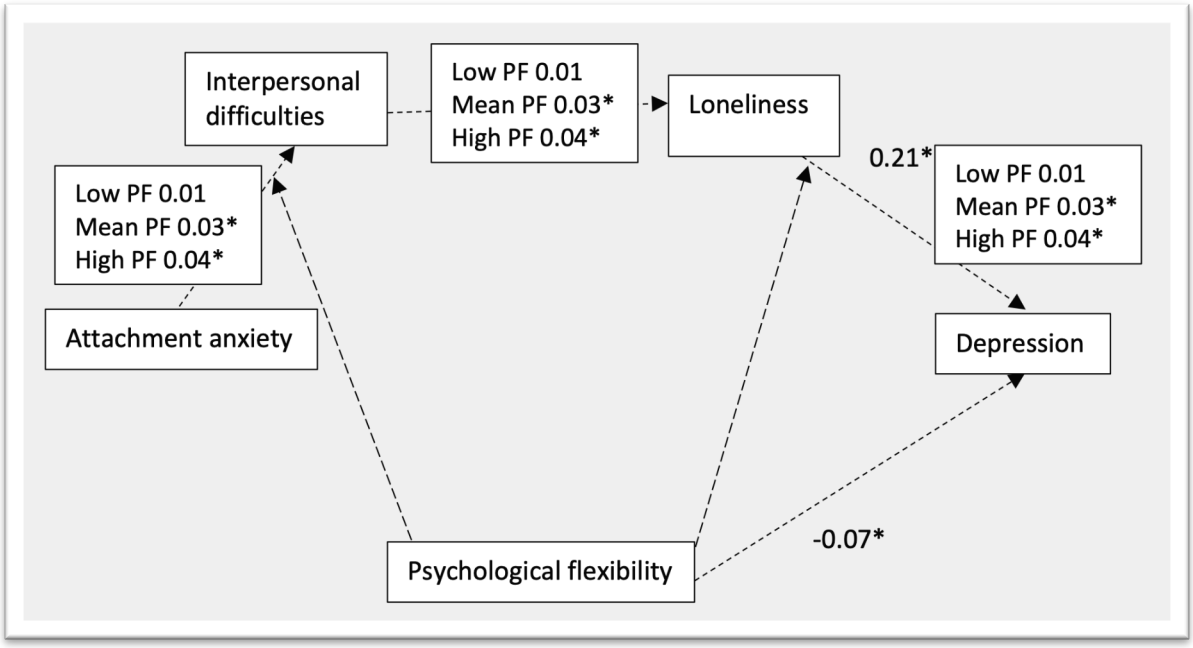

Figure 6. Graphical representation of conditional process analysis of relationship between attachment anxiety and depression

Key: ——► Direct effect ┈┈┈► Indirect effect - - - - - ► Moderated effect

*=p≤0.05 indicating the moderation effect of PF is stronger under high PF.

Numbers represent standardised β coefficients

The analysis was repeated, using QoL as the outcome variable, this model accounted for 48% of the variance, (R^2=0.48, F(7,109)=14.35, p<0.001). There was a significant indirect effect between attachment anxiety and QoL when PF was at mean or high levels (see Figure 7). Thus at low levels of PF, the predictors are merely associated with attachment anxiety, whereas at mean or high levels the relationship becomes more nuanced.

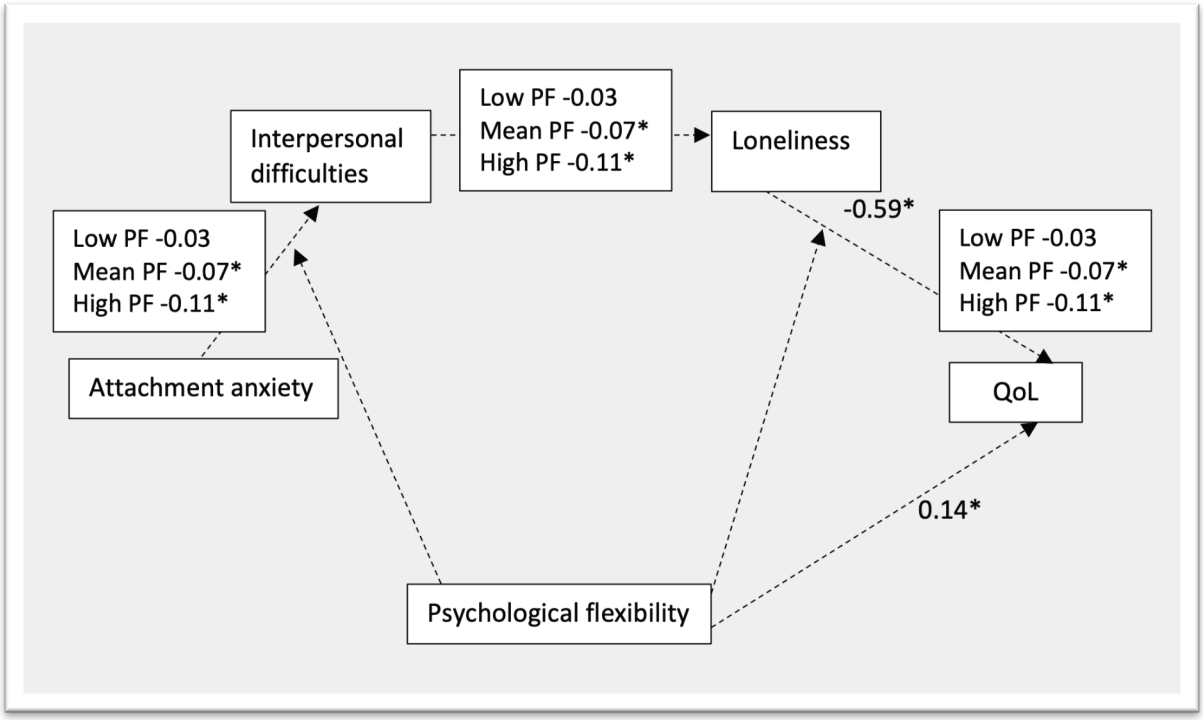

Figure 7. Graphical representation of conditional process analysis of relationship between attachment anxiety and QoL

Key: ——► Direct effect ┈┈┈► Indirect effect - - - - - ► Moderated effect

*p≤0.05 indicating the moderation effect of PF is stronger under high PF.

Numbers represent standardised β coefficients

Discussion

This was one of the first known studies to explore the factors that influence loneliness, mental health and QoL within an OA population. The aim of this study was to examine relationships between loneliness, anxiety, depression and QoL, and to examine whether attachment anxiety and interpersonal difficulties influence these relationships. In addition, the study investigated whether PF moderates these direct and indirect relationships. This study sought to further extend emerging evidence suggesting potential interactions between attachment anxiety, interpersonal processes and experiential avoidance (Gerhaert et al., 2014).

This study built upon evidence supporting the role of PF for promoting psychological well-being, specifically within the OA population. This study also sought to address the dearth of

research evidence identifying specific psychological factors associated with loneliness, to thereafter influence targeted interventions, within this population. The findings suggest that OA who are less psychologically flexible and experience loneliness as well as interpersonal difficulties are more likely to suffer from anxiety, depression and lower QoL, than their counterparts. The findings also suggested that interpersonal difficulties can influence whether an OA with attachment anxiety experiences anxiety or depression, dependent on how psychologically flexible they are.

Correlations were initially carried out to identify basic relationships between the variables. As expected, all variables were highly significantly correlated with each other. In particular, attachment anxiety had large positive correlations with anxiety and depression and a medium negative correlation with QoL, as hypothesised, thus fulfilling objective 1 of this study. However, despite QoL only having a moderate correlation, the strength of the relationship was similar to that of anxiety and depression. As expected, the relationship between attachment anxiety and QoL was negative, suggesting that the greater the attachment anxiety, the lower a person's QoL. Regression analyses were subsequently carried out, loneliness and PF were significant predictors of anxiety, depression and QoL. Again, it is interesting to note that despite the significant correlations between all of the variables, when entered into a regression, interpersonal difficulties was not a significant predictor in any of the models tested. It is possible that despite having predictive value, that the strength of the relationship between interpersonal difficulties and the outcome variables was not as strong as that between loneliness, PF and the outcome variables and thus when examined alongside these factors in a regression, it did not reach statistical significance.

It is interesting to note that when the simple mediations were carried out, only anxiety was directly affected by attachment anxiety. In the case of the relationship between attachment anxiety and depression and attachment anxiety and QoL, the total effect was significant, however, when this was partialled into its direct and indirect effects, only the indirect effect was significant. This suggests that PF, interpersonal difficulties and loneliness influence the impact that attachment anxiety may have on someone, as suggested by objective 2, warranting further investigation.

By using conditional process analysis, the effect of different levels of PF were explored. The findings concerning the relationship between attachment anxiety and anxiety were somewhat curious, such that it would appear that when people have low levels of PF, this affects how interpersonal difficulties explain the relationship between attachment anxiety and anxiety, in the case of mean PF, loneliness also becomes a significant mediator. However, when a person has high PF, it is only the distal factor of attachment anxiety that predicts anxiety, and not the proximal factors of interpersonal difficulties or loneliness. In the case of both depression and QoL, mean or high levels of PF moderated the relationship between attachment anxiety, interpersonal difficulties, loneliness and the outcome variable, suggesting that high PF buffers these pathways.

In this sample, attachment anxiety was positively correlated with anxiety and depression and negatively correlated with QoL as reported by others (Van Assche et al., 2013). In addition, attachment anxiety had an indirect effect on these three outcomes, through interpersonal functioning and loneliness. Of particular interest, the findings reported herein suggest that when a person has high PF, this may negate the impact of interpersonal difficulties and loneliness, such that under conditions of high PF, attachment anxiety has a direct effect on anxiety. It is possible that PF may reduce the mediation by the proximal factors, but cannot reduce the contribution of the distal factor, specifically, it is likely that PF cannot remove a person's learning history, however, it can alter a person's interpersonal behaviours and their sense of loneliness such that these factors no longer mediate, but despite this, a person may still have an anxious attachment. It is also important to point out that people with high PF may be more willing to experience anxiety as a function of being present and thus feeling anxious, may not have a negative impact on their overall well-being. In addition, this study did not take into account the influence of anxiety on a person's day-to-day functioning, such that a person with high PF, while experiencing anxiety may still live their lives in the service of their values. In comparison, a person with low or medium PF who may be less well connected with their values and more experientially avoidant, may also experience interpersonal difficulties and loneliness which may ultimately influence how anxious they are.

The moderating effects of PF as evidenced within this study highlight its importance for psychological well-being and suggests that different levels of PF have different effects on

outcomes and therefore well-being. In particular, the moderation of the relationship between attachment anxiety and QoL by PF, suggested that a difficult relationship history was less likely to have an impact on a person's QoL if they are psychologically flexible. Existing research highlights the moderating effect of PF on adjustment and well-being in various populations (McAteer & Gillanders, 2019; Fonseca et al., 2019; Gloster et al., 2017). Research has also suggested a mediating role of PF and engaged living in the case of the relationship between gratitude and loneliness (Frinking et al., 2019). This suggests that PF can function as both a moderator and mediator, despite this, the decision to use it as a moderator in the case of this study was in order to build on existing research examining experiential avoidance and interpersonal processes (Gerhart et al., 2014).

Furthermore, it would appear that loneliness, as hypothesised, was associated with increased anxiety and depression and lower QoL, as reported by others (Beutel et al., 2017). However, it is interesting to note that it was only when a person had mean or high levels of PF that loneliness mediated the relationship between attachment anxiety and the outcome variables. This may suggest that for people with attachment anxiety and interpersonal difficulties who are psychologically inflexible that the impact of these factors may be so great that whether or not they are lonely has no impact on whether they experience anxiety, depression or poor QoL.

Implications for policy

Emerging research evidence suggests that interventions targeting PF may be beneficial for those at risk of developing psychological difficulties (Levin et al., 2015). This current research adds support by suggesting that PF may help buffer against the negative impact of a difficult relationship history on anxiety, depression and QoL. However, prior to widespread dissemination of such interventions, they would need to be thoroughly researched and evidenced and support from policy makers would need to be in place. In particular, this research would need to focus on the specific OA-related issues. There is a body of existing interventions targeting aspects of PF, which could potentially usefully be adapted to suit the needs of OA and in particular, those at risk of loneliness. As well as traditional one-to-one therapy, group-based interventions have been shown to increase psychological flexibility and reduce distress (Brassington et al., 2016). Self-help interventions focusing on mindfulness

and acceptance have also been suggested to be beneficial (Cavanagh et al., 2014). In addition, eHealth interventions may help increase access to evidence-based ACT interventions and may be suited to those experiencing milder levels of distress (O'Conner et al., 2018). However, use of e-Health may require OA to be introduced to the technology to ensure they are comfortable with its use.

The findings outlined herein suggest that the solution to reducing levels of loneliness in OA and any associated effects it may have on psychological well-being may not necessarily lie in interventions to increase social connectedness, instead it may be more pertinent to try and focus on the psychological risk factors for loneliness and subsequent well-being. Indeed, while trying to increase social connectedness may benefit some people, it is likely that those with higher levels of interpersonal difficulties, as well as attachment anxiety may experience these interventions as threatening and thus they may be somewhat iatrogenic, or may be associated with high attrition rates. However, based on the findings outlined herein, it is likely that PF interventions could help mitigate this, thus allowing them to access such interventions, although it must be reiterated that this statement is based on findings from cross-sectional research and that further research could help add to this emerging evidence base.

Implications for research

Exploration of PF within the OA population is in its infancy and this study helps identify potential future research avenues. The research outlined in this paper is one of the first to explore the links between PF, attachment anxiety, interpersonal difficulties and loneliness in an OA population. The findings indicate that the included factors predict loneliness and psychological well-being in theoretically consistent ways. The findings suggest it may be useful to identify ways in which to increase PF amongst OA at risk of becoming lonely.

This study evidenced the relationship between a number of psychological factors and negative outcomes in an OA population. Existing research (Gerhart et al., 2014) evidenced a similar relationship between attachment style and loneliness. Thus, while the findings of this study are useful, it is not possible to say whether the model explored factors unique to this population, or whether it is likely that maladaptive interpersonal processes are formed at

another point in someone's life. Further research should be carried out to help identify specific points at which to intervene to help prevent against the development of attachment anxiety, interpersonal difficulties and loneliness. It would also be beneficial for future research to further explore the relationship between PF, attachment anxiety and anxiety to examine whether the findings reported herein are replicable. Lastly, future research should also address the influence of different attachment styles (e.g. hostile, secure) on subsequent loneliness.

This study examined PF as a whole, it could be beneficial to identify the impact of the different components of the hexaflex, such as cognitive fusion, on OA loneliness. This could involve the use of different measures to help further the science in this area and may suggest that specific approaches targeting specific components of the ACT model may be more efficacious for this population.

This sample included community-dwelling OA, future research could build on these findings by also including those living in residential facilities to identify whether this influences levels of loneliness. Similarly, including people with chronic physical health conditions may also be beneficial, to identify any potential links.

Implications for training

Given the findings of this research and the strong influence that high levels of PF can have on psychological well-being, it is suggested that those working with OA should be provided with the skills and knowledge to help this population become more psychologically flexible and thus prevent some of the potential negative outcomes associated with loneliness and historical and interpersonal issues.

Implications for practice

The findings add further support to the link between attachment style and interpersonal difficulties, this research suggests that PF may moderate this relationship, dependent on how psychologically flexible a person is. The relationship between attachment anxiety and anxiety was mediated by interpersonal difficulties and moderated by PF in the case of those with low or mean levels of PF. Similarly, PF moderated the relationship between attachment anxiety,

interpersonal processes, loneliness and QoL. These findings suggest that PF may be a clear treatment target when working with OA, as this may help protect against the development of mental health difficulties. In addition, research suggests that attachment anxiety can be influenced by experience, indicating that it could be addressed via psychological intervention (Van Assche et al., 2013). In the case of people with a desire for increased connectedness with others but a history of negative experiences of relationships, psychological flexibility work may be beneficial. Furthermore, literature suggests that in the OA population, ACT may be a more suitable treatment approach due to its focus on valued action (Petkus & Wetherell, 2013), rather than the specific amelioration of psychological distress, this taken with the findings of this study, support the potential role of ACT within this population. Furthermore, recent research suggests that ACT used alongside the selection, optimisation and compensation (SOC) model of successful ageing (Baltes & Baltes, 1990) can lead to positive outcomes amongst older adults (Alonso et al., 2016; 2013). The SOC approach views the ageing process as filled with various gains and losses and suggests that by selecting meaningful goals, compensating for losses and optimising performance of these goals, this can lead to successful ageing. It is clear that both ACT and SOC have similar underlying philosophies of helping someone maintain valued activity in spite of the difficulties they face and this emerging evidence suggests the useful integration of these approaches.

Limitations

This study included a focus on attachment anxiety, rather than attachment as a whole, which potentially limits the scope of the findings. It was felt from the literature review that attachment anxiety was potentially the most relevant form of attachment to the development and maintenance of loneliness. While the investigation of secure attachment may have been interesting, that would have potentially changed the focus of the study. In addition, during the development of the study, the authors were keen to keep measures short so as to not over-burden participants.

It is likely that there may be a number of limitations as a result of the included sample, as evidenced in table 1 in the results section, likely as a result of the recruitment strategy employed, which may have influenced the findings outlined herein. The included sample was not particularly lonely or isolated. Furthermore, most of the sample consisted of women who

were cohabiting, which again potentially influenced the outcomes of this research and subsequent recommendations. Specifically, it is likely that the older women in relationships may have a different attachment experience and history of successfully relating to others compared to their single counterparts, or to men. In addition, it is likely that the mental health and QoL outcomes may also have been different for this select group of women. Lastly, as the sample all lived in the community, it is possible that they were all relatively healthy, which again could have influenced their levels of loneliness and also their mental health.

As this was a cross-sectional study, as such it only accounted for a single point in time, had a longitudinal or cohort study been carried out, this may have provided a different set of findings. It is likely that a person's level of loneliness as well as the mental health consequences may fluctuate, which it was not possible to capture using the methodology described chosen.

Some of the variables included data that was not normally distributed; however, realistically this reflects the increased likelihood of people who are not experiencing mental health difficulties engaging with such research. Despite this, when comparing this sample to other populations using the same measures (see table 2), mean responses were broadly similar for most items, apart from interpersonal difficulties, of which this sample experienced higher levels, and anxiety and depression, of which this sample reported lower levels. It is also likely that recruiting via third-sector groups may have potentially influenced the types of people participating, in terms of demographics or mental health difficulties.

The models that were tested were based on a priori hypotheses and were also shaped by the earlier step-by-step analysis process employed. It is likely that other models could be equally valid in this cross-sectional data, which would have implications for the overall findings.

Lastly, this study only included OA living within the community, it is possible that the findings may have been different had people living in care homes been included. Similarly, almost two-thirds of the sample were married and roughly three-quarters lived with somebody, which may also have influenced findings given current understanding of attachment anxiety and interpersonal difficulties.

Conclusion

This study set out to examine relationships between loneliness, anxiety, depression and QoL, and to examine whether attachment anxiety and interpersonal difficulties mediated these relationships. The study also investigated whether Psychological Flexibility moderated these direct and indirect relationships. Using conditional process analysis, this study showed that interpersonal difficulties and loneliness mediated the relationship between attachment anxiety and anxiety, depression and QoL in a sample of community-dwelling OA. This study also provided further evidence for the moderating role of PF and its relationship with psychological well-being.

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Engle, E.K., Cash, T.F., & Jarry, J.L. (2009, November). The Body Image Behaviours Inventory-3: Development and validation of the Body Image Compulsive Actions and Body Image Avoidance Scales. Poster session presentation at the meeting of the Association for Behavioural and Cognitive Therapies, New York, NY.

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THE UNIVERSITY of EDINBURGH

Participant Information Leaflet

Study title: Loneliness in Older People

An invitation to participate in a research study

We are carrying out a research study to try and find out what causes older people to become lonely. Before you decide to take part, we would like you to understand why this research is being carried out and what it would involve for you. *Please note that you do not need to be feeling lonely to participate*.

What is this study about?

There is a lot of evidence to suggest that feeling lonely can have a negative effect on our health and well-being. Loneliness can be described as a negative feeling we experience when we do not have the quality and quantity of close relationships and social connections we would like to have. As we get older we can be at more risk of becoming lonely due to the changes that can happen at this stage of life (such as retirement and bereavement, for example). The purpose of this study is to try to understand what factors might increase an older person's risk of experiencing long-term loneliness and what the impact might be on their health and well-being. We would like to know how a few things influence whether people feel lonely, these are:

1. Whether we do the things that are important to us, when life makes this difficult,
2. How we act around other people and form relationships with them.

We would also like to understand more about how older people feel about their everyday lives, including the activities they take part in, their relationships with others and how happy they feel.

We would like to gather this information by asking older people to fill out some brief questionnaires. We would like to hear from people from all walks of life and you do not need to be lonely to take part. This will help us understand the things that may influence loneliness. With this information, we hope to be able to reduce the risk of loneliness becoming an issue for older people and to support those who may already be struggling with the experience of loneliness.

Why have I been invited?

We are asking people, all people over the age of 60, or who are retired to take part in this research, you do not need to be feeling lonely to take part.

Do I have to take part?

No, you do not have to participate. Deciding not to take part will not affect any current or future care you receive. As we will not be asking you to give us your name or any other identifiable information, it will not be possible for you to withdraw your information from the study once you have submitted your questionnaire.

What happens if I decide to take part in the study?

You can take as long as you like to decide whether you would like to take part.

You will be asked to fill out one questionnaire with seven separate sections which focus on the following areas:

1. Whether you continue to do the things that are important to you, particularly when changes occur that make this more difficult
2. Your relationships with others

You will also be asked to complete some questions about your age, gender, marital status and whether you go to any community groups.

It should take you approximately 30 minutes to complete the questionnaire. The questionnaire is available online, as well as in paper form. Before you start to complete the questionnaire, we would like you to tick a box at the top of the form to let us know that you consent to take part.

What do I do next?

If you decide you would like to take part, once you have read all of this leaflet and feel that you have understood the information provided, please complete the attached questionnaire and return it in the envelope provided. At the start of the questionnaire you will be asked to tick a box to say that you agree to take part in this study. If you have any questions, please contact Deirdre Holly, using the details below. If you would like to discuss this study with someone independent of the study team please contact: Dr. John Higgon on: 01387 244 495 or email: john.higgon@nhs.net

You can take as long as you like to consider if you would like to participate. If you would prefer to fill out the questionnaire online, you can find it here: https://edinburgh.onlinesurveys.ac.uk/loneliness-in-older-adults

Will my taking part in the study be kept confidential?

All information which is collected about you during the course of the research will be kept strictly confidential, this means that we will not be telling anybody else

that you have taken part in this study and that only those who should be accessing the information you have provided will be able to do so. As we will not ask you to give us your name or any other identifiable information, it will not be possible to identify any of your responses. Your information will be stored on a computer with a password that only the research team know. Your responses will be put on a file with other people's responses to help us better understand the issue of loneliness in older people. Your confidentiality will be respected throughout this study.

What will happen to the results of this study?

A final report will be written up and submitted to the University of Edinburgh as part of the researcher's (Deirdre Holly) training to become a clinical psychologist. It is also possible that the results of this study may be presented at a conference or in an academic journal article, which will help others learn about what affects loneliness in older people. It will not be possible to identify any of the information you provided.

What are the possible disadvantages and risks of taking part?

For some people, thinking about their own life and whether they feel connected to other people may be upsetting, however, we have included the details of people and groups who could help you if you do become upset, below.

The questionnaire may take you up to 30 minutes to complete, which for some people might be a bit tiring.

What are the possible benefits of taking part?

Quite often people find that having time to think about their lives can be a positive experience.

Who has reviewed this study?

All research in the NHS is looked at by an independent group of people called a Research Ethics Committee. This study has been given a favourable opinion by the South Central - Berkshire Research Ethics Committee (18/SC/0599, Date 23.10.18). NHS Management approval has also been obtained (18/DGY/029, Date 05.11.18).

What if taking part in this study raises concerns about my own feelings of loneliness?

Some useful organisations for meeting other older people are:
Kate's Kitchen-01461 206 444
University of the Third Age-https://www.u3a.org.uk/find
Men's Shed-07397 382533
FoodTrain Friends-01387 270800

If taking part in this research makes you feel upset or distressed and you would like to speak to someone you can call:
Breathing Space-0800 83 85 87 (a Scottish based support line for anyone struggling with their mental health or well being)
The Silver Line: 0800 4 50 60 70 (a support and advice line for older people)
The Samaritans-01387 253555

Further information on sources of support are provided in the 'Beating the Lows in Later Life' leaflet enclosed.

If you become upset or distressed during or after taking part in this study and feel you might need some additional, specialist support, please speak to your GP.

What if there is a problem?

If you are unhappy about aspects of this study and wish to complain formally, you can do this through the NHS Complaints Procedure, please contact: Patient Services Team, NHS Dumfries and Galloway, Logan West, Crichton Hall, Dumfries, DG1 4TG. Tel: 01387 272733

Researcher contact details

Ms. Deirdre Holly, Trainee Clinical Psychologist
Dept. of Psychological Services and Research,
Crichton Hall, DG1 4TG
NHS Dumfries & Galloway
T: 01387 244 495
E: deirdreholly@nhs.net

Dr. Fionnuala Edgar, Clinical Psychologist
Dept. of Psychological Services and Research,
Crichton Hall, DG1 4TG
NHS Dumfries & Galloway
T: 01387 244 495

Dr. David Gillanders, Clinical Psychologist
Doctoral Programme in Clinical Psychology
University of Edinburgh
School of Health in Social Science
Teviot Place
Edinburgh, EH8 9AG
T: 0131 651 3946

Loneliness in Older People

Project Questionnaire

I agree to participate in this research study (please tick) ☐
What is your age?
Are you a: Man Woman Other Prefer not to say
Are you: Married/Civil partnership/Co-habiting Widowed In a relationship Single Divorced/Separated Prefer not to say Other (please state)
Do you have any children? Yes No Prefer not to say
Who do you live with? (circle all that apply) Husband/Wife/Partner Parent Other family member(s) Children I live alone Lodger/tenant Other (please state) Prefer not to say
Do you attend any community groups? Yes No Prefer not to say
Are you currently employed (paid or voluntary)?

We would like to ask you about your quality of life:

Single item - global QoL:

1 Thinking about both the good and bad things that make up your quality of life, how would you rate the quality of your life as a whole?

Your quality of life as a whole is:	Very good	Good	Alright	Bad	Very bad
	☐	☐	☐	☐	☐

OPQOL-Brief

2 Please tick one box in each row. Please select the response that best describes you/your views. There are no right or wrong answers.

	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree
1 I enjoy my life overall	☐	☐	☐	☐	☐
2 I look forward to things	☐	☐	☐	☐	☐
3 I am healthy enough to get out and about	☐	☐	☐	☐	☐
4 My family, friends or neighbours would help me if needed	☐	☐	☐	☐	☐
5 I have social or leisure activities/ hobbies that I enjoy doing	☐	☐	☐	☐	☐
6 I try to stay involved with things	☐	☐	☐	☐	☐
7 I am healthy enough to have my independence	☐	☐	☐	☐	☐
8 I can please myself what I do	☐	☐	☐	☐	☐
9 I feel safe where I live	☐	☐	☐	☐	☐
10 I get pleasure from my home	☐	☐	☐	☐	☐
11 I take life as it comes and make the best of things	☐	☐	☐	☐	☐
12 I feel lucky compared to most people	☐	☐	☐	☐	☐
13 I have enough money to pay for household bills	☐	☐	☐	☐	☐

Tick the box beside the reply that is closest to how you have been feeling in the past week.
Don't take too long over you replies: your immediate is best.

D	A		D	A	
		I feel tense or 'wound up':			**I feel as if I am slowed down:**
	3	Most of the time	3		Nearly all the time
	2	A lot of the time	2		Very often
	1	From time to time, occasionally	1		Sometimes
	0	Not at all	0		Not at all
		I still enjoy the things I used to enjoy:			**I get a sort of frightened feeling like 'butterflies' in the stomach:**
0		Definitely as much		0	Not at all
1		Not quite so much		1	Occasionally
2		Only a little		2	Quite Often
3		Hardly at all		3	Very Often
		I get a sort of frightened feeling as if something awful is about to happen:			**I have lost interest in my appearance:**
	3	Very definitely and quite badly	3		Definitely
	2	Yes, but not too badly	2		I don't take as much care as I should
	1	A little, but it doesn't worry me	1		I may not take quite as much care
	0	Not at all	0		I take just as much care as ever
		I can laugh and see the funny side of things:			**I feel restless as I have to be on the move:**
0		As much as I always could		3	Very much indeed
1		Not quite so much now		2	Quite a lot
2		Definitely not so much now		1	Not very much
3		Not at all		0	Not at all
		Worrying thoughts go through my mind:			**I look forward with enjoyment to things:**
	3	A great deal of the time	0		As much as I ever did
	2	A lot of the time	1		Rather less than I used to
	1	From time to time, but not too often	2		Definitely less than I used to
	0	Only occasionally	3		Hardly at all
		I feel cheerful:			**I get sudden feelings of panic:**
3		Not at all		3	Very often indeed
2		Not often		2	Quite often
1		Sometimes		1	Not very often
0		Most of the time		0	Not at all
		I can sit at ease and feel relaxed:			**I can enjoy a good book or radio or TV program:**
	0	Definitely	0		Often
	1	Usually	1		Sometimes
	2	Not Often	2		Not often
	3	Not at all	3		Very seldom

Please check you have answered all the questions

CompACT

Name:	Date:

Please rate the following 23 statements using the scale below:

0	1	2	3	4	5	6
Strongly disagree	Moderately disagree	Slightly disagree	Neither agree nor disagree	Slightly agree	Moderately agree	Strongly agree

1. I can identify the things that really matter to me in life and pursue them	0	1	2	3	4	5	6
2. One of my big goals is to be free from painful emotions	0	1	2	3	4	5	6
3. I rush through meaningful activities without being really attentive to them	0	1	2	3	4	5	6
4. I try to stay busy to keep thoughts or feelings from coming	0	1	2	3	4	5	6
5. I act in ways that are consistent with how I wish to live my life	0	1	2	3	4	5	6
6. I get so caught up in my thoughts that I am unable to do the things that I most want to do	0	1	2	3	4	5	6
7. I make choices based on what is important to me, even if it is stressful	0	1	2	3	4	5	6
8. I tell myself that I shouldn't have certain thoughts	0	1	2	3	4	5	6
9. I find it difficult to stay focused on what's happening in the present	0	1	2	3	4	5	6
10. I behave in line with my personal values	0	1	2	3	4	5	6
11. I go out of my way to avoid situations that might bring difficult thoughts, feelings, or sensations	0	1	2	3	4	5	6
12. Even when doing the things that matter to me, I find myself doing them without paying attention	0	1	2	3	4	5	6
13. I am willing to fully experience whatever thoughts, feelings and sensations come up for me, without trying to change or defend against them	0	1	2	3	4	5	6
14. I undertake things that are meaningful to me, even when I find it hard to do so	0	1	2	3	4	5	6
15. I work hard to keep out upsetting feelings	0	1	2	3	4	5	6
16. I do jobs or tasks automatically, without being aware of what I'm doing	0	1	2	3	4	5	6
17. I am able to follow my long terms plans including times when progress is slow	0	1	2	3	4	5	6
18. Even when something is important to me, I'll rarely do it if there is a chance it will upset me	0	1	2	3	4	5	6
19. It seems I am "running on automatic" without much awareness of what I'm doing	0	1	2	3	4	5	6
20. Thoughts are just thoughts – they don't control what I do	0	1	2	3	4	5	6
21. My values are really reflected in my behaviour	0	1	2	3	4	5	6
22. I can take thoughts and feelings as they come, without attempting to control or avoid them	0	1	2	3	4	5	6
23. I can keep going with something when it's important to me	0	1	2	3	4	5	6

People have reported having the following problems in relating to other people. Please read the list below, and for each item, consider whether it has been a problem for you with respect to any significant person in your life. Then choose the response that best describes how distressing that problem has been. The following are things you find hard to do with other people.

It is hard for me to:

	Not at all	Slightly	Somewhat	Moderately	Very
Say "no" to other people	☐	☐	☐	☐	☐
Join in on groups	☐	☐	☐	☐	☐
Keep things private from other people	☐	☐	☐	☐	☐
Tell a person to stop bothering me	☐	☐	☐	☐	☐
Introduce myself to new people	☐	☐	☐	☐	☐
Confront people with problems that come up	☐	☐	☐	☐	☐
Be assertive with another person	☐	☐	☐	☐	☐
Let other people know when I am angry	☐	☐	☐	☐	☐
Socialize with other people	☐	☐	☐	☐	☐
Show affection to people	☐	☐	☐	☐	☐
Get along with people	☐	☐	☐	☐	☐
Be firm when I need to be	☐	☐	☐	☐	☐
Experience a feeling of love for another person	☐	☐	☐	☐	☐
Be supportive of another person's goals in life	☐	☐	☐	☐	☐
Feel close to other people	☐	☐	☐	☐	☐
Really care about other people's problems	☐	☐	☐	☐	☐
Put somebody else's needs before my own	☐	☐	☐	☐	☐
Feel good about another person's happiness	☐	☐	☐	☐	☐

Ask other people to get together socially with me	☐ ☐ ☐ ☐ ☐
Be assertive without worrying about hurting the other person's feelings	☐ ☐ ☐ ☐ ☐

The following questions are about things you do too much:

	Not at all	Slightly	Somewhat	Moderately	Very
I open up to people too much	☐	☐	☐	☐	☐
I am too aggressive toward other people	☐	☐	☐	☐	☐
I try to please other people too much	☐	☐	☐	☐	☐
I want to be noticed too much	☐	☐	☐	☐	☐
I try to control other people too much	☐	☐	☐	☐	☐
I put other people's needs before my own too much	☐	☐	☐	☐	☐
I am overly generous to other people	☐	☐	☐	☐	☐
I manipulate other people too much to get what I want	☐	☐	☐	☐	☐
I tell personal things to people too much	☐	☐	☐	☐	☐
I argue with other people too much	☐	☐	☐	☐	☐
I let other people take advantage of me too much	☐	☐	☐	☐	☐
I am affected by another person's misery too much	☐	☐	☐	☐	☐

The following statements are about your contact with other people, please indicate how often each of the statements below is descriptive of you:

I lack companionship.	Often	Sometimes	Rarely	Never
There is no one I can turn to.	Often	Sometimes	Rarely	Never
I am an outgoing person.	Often	Sometimes	Rarely	Never
I feel left out.	Often	Sometimes	Rarely	Never

I feel isolated from others.	Often	Sometimes	Rarely	Never
I can find companionship when I want it.	Often	Sometimes	Rarely	Never
I am unhappy being so withdrawn.	Often	Sometimes	Rarely	Never
People are around me but not with me	Often	Sometimes	Rarely	Never

The following are statements about how people feel about their relationships with other people, please indicate how much each of the statements below is like you:

	Not at all	Slightly	Somewhat	Moderately	Very
I usually feel quite anxious about my intimate relationships.	☐	☐	☐	☐	☐
It takes me time to get over my shyness in a new close relationship	☐	☐	☐	☐	☐
Intimate relationships make me feel nervous and anxious	☐	☐	☐	☐	☐
I am somewhat awkward and tense in intimate relationship	☐	☐	☐	☐	☐
I feel nervous when I interact with a partner in an intimate relationship	☐	☐	☐	☐	☐
I am more anxious about intimate relationships than most people are	☐	☐	☐	☐	☐
I feel uncomfortable when I think about talking with an intimate partner	☐	☐	☐	☐	☐
I would feel inhibited and shy in an intimate relationship	☐	☐	☐	☐	☐
I would feel anxious in a new intimate relationship	☐	☐	☐	☐	☐

Thank you very much for taking the time to complete this questionnaire!

Health Research Authority

South Central - Berkshire Research Ethics Committee
Bristol REC Centre
Whitefriars
Level 3, Block B
Lewins Mead
Bristol
BS1 2NT

Telephone: (020) 71048043

Please note: This is an acknowledgement letter from the REC only and does not allow you to start your study at NHS sites in England until you receive HRA Approval

29 October 2018

Ms Deirdre Holly
Dept. of Psychological Services & Research
Queensberry East
Crichton Hall, Dumfries
DG1 4TG

Dear Ms Holly

Study title: **Psychological flexibility and its relationship with loneliness in older people**
REC reference: **18/SC/0599**
IRAS project ID: **250843**

Thank you for your letter of 23 October 2018. I can confirm the REC has received the documents listed below and that these comply with the approval conditions detailed in our letter dated 23 October 2018

Documents received

The documents received were as follows:

Document	*Version*	*Date*
Participant information sheet (PIS) [LIOP PIS]	1.1	27 October 2018

Approved documents

The final list of approved documentation for the study is therefore as follows:

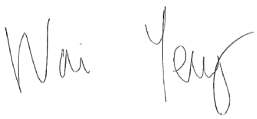
Document	*Version*	*Date*

Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Insurance & Indemnity]		31 July 2018
IRAS Application Form [IRAS_Form_11102018]		11 October 2018
Other [Insurance & Indemnity]		01 August 2018
Other [Insurance & Indemnity]		24 July 2018
Other [Insurance & Indemnity]		31 July 2018
Participant information sheet (PIS) [LIOP PIS]	1.1	27 October 2018
Research protocol or project proposal [LIOP Protocol]	1.0	05 October 2018
Summary CV for Chief Investigator (CI) [CI CV]		05 October 2018
Summary CV for student [CI/Student CV]		
Summary CV for supervisor (student research) [Academic Supervisor CV]		
Validated questionnaire [LIOP Questionnaire]		

You should ensure that the sponsor has a copy of the final documentation for the study. It is the sponsor's responsibility to ensure that the documentation is made available to R&D offices at all participating sites.

18/SC/0599 **Please quote this number on all correspondence**

Yours sincerely



Wai Yeung
REC Assistant

E-mail: nrescommittee.southcentral-berkshire@nhs.net

Research and Development Support Unit
Ground Floor
Dumfries and Galloway Royal Infirmary
Bankend Road
Dumfries
DG1 4AP

NHS
Dumfries
& Galloway

Ms Deidre Holly
Dept of Psychological Services
Queensberry East
Crichton Hall
DUMFRIES
DG1 4TG

Date: 5th November 2018
Our ref: JC/LMM/18/DGY/029

Study title: LONELINESS IN OLDER PEOPLE
Protocol version approved: v1 Dated: 05/10/2018
Amendments included: n/a

Dear Ms Holly

Thank you for sending me details of your study with a request for management approval. I can confirm that the study review team has reviewed the documentation and on this basis I am pleased to inform you that your study has management approval for commencement within NHS Dumfries and Galloway.

It is a condition of this approval that everyone involved in this study abides by the guidelines/protocols laid down by this Health Board in respect of confidentiality and Research Governance. It is your responsibility to ensure you are familiar with these; please do not hesitate to seek advice if you are unsure. Copies of Research Governance Framework documents are available via the website www.sehd.scot.nhs.uk/cso and then use the publications link.

We also note that it is the sponsor's responsibility to ensure that appropriate training is in place for all local investigators. It is important that all research must be carried out in compliance with the Research Governance Framework for Health and Community Care and the new EU Clinical Trials Directive (for clinical trials involving investigational medicinal products).

As part of the Health Board's responsibilities under Research Governance a sample of studies will be monitored, and it is therefore important that all records in connection with the study are kept up to date and available for review. We are also required to inform you that details of your study will be entered onto our R&D database. As custodian of the information collated during this research project, you are responsible for ensuring the security of all personal information collected, in line with NHS Scotland IT Security Policies, until the destruction of this data.

Research and Development Support Unit
Ground Floor
Dumfries and Galloway Royal Infirmary
Bankend Road
Dumfries
DG1 4AP

NHS
Dumfries
& Galloway

If your study is adopted by UKCRN into a portfolio then please advise this department of recruitment figures by adding accrual data to that database on a monthly basis.

Please notify the R&D office immediately you become aware of any serious adverse events associated with this research.

You must contact the R&D Department if/when the project is subject to any minor or substantial amendments so that these can be appropriately assessed, and approved, where necessary. I understand that performance of this study will not infringe on NHS Dumfries and Galloway's ability to deliver our usual level of service.

May I take this opportunity to wish you every success with your project. Please do not hesitate to seek help and advice from the R&D Support Unit (ext 33165/33815) if there is anything you feel you require assistance with. I look forward to hearing about your work and would appreciate a short annual report and a final report when the study is complete.

Yours Sincerely

Janie Candlish

Mrs Janie Candlish
Clinical Trials/Research Project Manager

cc: SREDA Database
De David Gillanders
Charlotte Smith

Non-CTIMP Study Protocol

Psychological Flexibility and its relationship with loneliness in older adults

	The University of Edinburgh College of Arts, Humanities and Social Sciences 55 George Square Edinburgh EH8 9JU
Protocol authors	**Deirdre Holly**
Chief Investigator	**Deirdre Holly, Trainee Clinical Psychologist**
Sponsor number	CAHSS1809/08
REC Number	**18/SC/0599**
Version Number and Date	**Version 1.0 05.10.2018**

Amendment classification and number: **E.g. non-substantial amendment 01 Jan 2000** **Or** **Substantial amendment 01: 01 Jan 2000**	**Summary of change(s)** **Please supply a brief summary of the change to the protocol**

CONTENTS

To update the table of contents, highlight the existing table of contents; right click "update fields" and OK

LIST OF ABBREVIATIONS

Insert abbreviations as required

LIST OF ABBREVIATIONS

ACCORD	Academic and Clinical Central Office for Research & Development - Joint office for The University of Edinburgh and Lothian Health Board
CI	Chief Investigator
CRF	Case Report Form
GCP	Good Clinical Practice
ICH	International Conference on Harmonisation
PI	Principal Investigator
QA	Quality Assurance
REC	Research Ethics Committee

INTRODUCTION

1.1 BACKGROUND

As the population grows older and people are living longer, it is important to identify the factors that may impede good psychological health and to develop approaches that can be used to alleviate these factors.

Loneliness

Loneliness can be described as a subjective, unpleasant and distressing phenomenon resulting from a discrepancy between an individual's desired and achieved levels of social relations (Perlman & Peplau, 1982). In terms of specific age groups most likely to experience loneliness, findings are mixed, however, some research suggests that within the OA population, those over the age of 75, may be more likely to experience loneliness (Richard, Rohrmann, Vandeleur, Schmid, Barth, Eichholzer, 2017). Research suggests that there may be three key pathways by which loneliness can affect health (Valtorta, Kanaan, Gilbody, Ronzi, Hanratty, 2016):

1. Health risk behaviours,
2. Defective immune functioning,
3. Psychological variables.

Health risk behaviours

Research suggests that within the general population, loneliness may be related to a host of negative outcomes, including long-term conditions (OR 1.41, 95% CI 1.30-1.54) and self-perceived ill health (OR 1.94, 95% CI 1.74-2.16), which may not be surprising, given that those who report being lonely are more likely to be smokers (OR 1.13, 95% CI 1.05–1.23), are more likely to be physically inactive (OR 1.20, 95% CI 1.10–1.31) and are more likely to have an unhealthy diet (OR 1.21, 95% CI 1.07–1.37) and thus generally have a poorer lifestyle than their non-lonely counterparts (Richard et al., 2017).

Defective immune functioning

Loneliness may be a risk factor for increased vascular resistance and high blood pressure (Cacioppo, Hawkley, Crawford, et al., 2002), altered gene expression suggestive of decreased inflammatory control and increased glucocorticoid insensitivity (Cole, Hawkley, Arevalo, & Cacioppo, 2011) as well as metabolic syndrome (Whisman, 2010) and poor and fragmented sleep (Cacioppo, Hawkley, Berntson, et al., 2002). A recent systematic review suggested that loneliness may even be associated with a 29% increase in risk of incident coronary heart disease and a 32% increase in risk of stroke (Valtorta et al., 2016). As a result, it may be no surprise that feelings of loneliness are associated with an increased risk of mortality over a six-year period, regardless of objective features of social relationships or health behaviours (Cacioppo & Cacioppo, 2014).

Psychological variables

In addition to the above, loneliness may have a detrimental impact on a person's quality of life, as a result of the associated to moderate to high levels of psychological distress (OR 3.74, 95% CI 3.37-4.16), depression (OR 2.78, 95% CI 2.22-3.48; Richard et al., 2017), generalised anxiety (OR = 1.21, 95% CI 1.09-1.34) and suicidal ideation (OR = 1.31, 95% CI 1.19-1.44; Beutel, Klein, Braehler, Reiner, Junger…Tibubos, 2017).

Psychological Flexibility

Psychological flexibility (PF) is a transdiagnostic concept, which underpins Acceptance and Commitment Therapy and can be described as the ability to "recognize and adapt to various situational demands; shift mindsets or behavioral repertoires when these strategies compromise personal or social functioning; maintain balance among important life domains; and be aware, open, and committed to behaviors that are congruent with deeply held values" (Kahsdan & Rottenberg, 2010). PF consists of six core processes, namely acceptance, cognitive defusion, being present, self as context, values and committed action, which can be used to develop intervention techniques and strategies. In a meta-

analysis of 66 component studies invoking PF (Levin, Hildebrandt, Lillis & Hayes, 2006), findings suggested that greater effects were found for the components of the model, in comparison to inactive conditions.

While all six processes of PF are important for a person's well-being, experiential avoidance, may in particular be relevant when factors such as loneliness are considered. Specifically, experiential avoidance is defined as the tendency to negatively evaluate and avoid difficult private events and thus, if someone has difficulties forming relationships with others, this may be something that they shy away from, indeed, research suggests that experiential avoidance may influence interpersonal problems and thus the relationships that someone may form with others (Gerhart, Baker, Hoerger & Ronan, 2014). As well as this, avoidance behaviours may have a negative impact on a person's goals, as a result of interpersonal problems (Holtforth, Bents, Mauler & Grawe, 2006) and may be associated with depression and anger (Gerhart, Heath, Fitzgerald & Hoerger, 2013). Moreover, an increase in experiential avoidance may result in an inability to achieve one's valued actions and result in someone becoming psychological inflexible (Gerhart et al., 2014).

Research suggests that PF may moderate the relationship between stress and physical health, mental health and well-being within the general population (Gloster, Meyer & Lieb, 2017); of note, one of the factors that was explored within this research was low perceived social support. This suggests that PF may be useful for protecting against the ill effects of loneliness, as outlined above and more generally, for promoting recovery and positive mental health (Slade, 2010) by allowing someone to avoid becoming stuck in a cycle of unhelpful behaviours, which take them away from attempting to achieve what is important to them, when they are experiencing difficulties.

Interpersonal processes

Building on the discussion of the potential utility of exploring the relationship between PF, and in particular experiential avoidance and loneliness within this population, research suggests that interpersonal theory may be beneficial for explaining the interpersonal behaviours that may occur as a result of experiential avoidance (Barkum, Hardy & Startup, 1996). The interpersonal circumplex, which is key to this theory, suggests that interpersonal problems may in fact be learned behaviours which fall on two intersecting dimensions, namely cold versus warmth and dominance versus submission. Interpersonal problems may arise should someone demonstrate excessive amounts of dominance or coldness, which may result in them having difficulties forming meaningful relationships with others, in particular, one of these difficulties may be social avoidance which may prevent the person from reaping the benefits of social contact with others and lead to them becoming lonely. Research suggests that attachment anxiety and hostility may mediate the relationship between experiential avoidance and interpersonal problems, such that experiential avoidance may interact with attachment anxiety and hostility to predict higher levels of interpersonal problems (Gerhart et al., 2014).

Attachment styles

The relationships people form with others and the approaches taken to do so, may have implications for subsequent loneliness, as suggested above, particularly hostile or anxiously attached people may have difficulties forging relationships. Much of the research on attachment styles has looked at the extension of attachment theory to adult romantic relationships (Hazan & Shaver, 1987). Research suggests that fear of rejection by others may lead someone to downplay their interests in other people, who unaware of this fear, may thus be less likely to forge a relationship with them, romantic, or otherwise (Vorauer, Cameron, Holmes & Pearce, 2003). Within the older adult population, attachment style can have important implications for how people relate to others, especially given the many changes that come with this period of life, such as retirement and the death of close others, as well as the birth of grandchildren, suggesting a change in attachment figures during this period (Doherty & Feeney, 2004). In terms of attachment anxiety, which may be of particular relevance to loneliness (Gerhart et al., 2014), findings from research examining this during older adulthood suggest it may decrease, increase or remain stable, depending on a person's experiences (Van Assche, Luyten, Bruffaerts, Persoons, van de Ven, & Vandenbulcke et al., 2013). Despite this, research suggests that attachment anxiety in older adults may be negatively related to self-reported well-being and thus may have deleterious impact on

a person's mental health, however, it has been indicated that social support may moderate this relationship (Van Assche et al., 2013).

1.2 RATIONALE FOR STUDY

From the research outlined above, it can be said that loneliness clearly has a detrimental impact on one's health, both physical and mental. There may be a number of factors that can influence whether someone develops loneliness, such as their attachment styles, how psychologically flexible they are and the interpersonal processes they engage in. A recent study (Gerhart et al., 2014) provided some provisional evidence to support these potential interactions, it is proposed that this may be usefully used to inform research to explore the factors that influence loneliness within an older adult population. The findings of this research would be a first step towards identifying factors that influence loneliness in older adults from this perspective and the findings could be used to inform treatment targets and to help identify those at risk of developing loneliness.

STUDY OBJECTIVES

1.3 OBJECTIVES

1.3.1 Primary Objective

To identify the factors associated with loneliness in an older adult population and the subsequent impact that loneliness can have on psychological well-being (quality of life, anxiety and depression).

1.3.2 Secondary Objectives

Does attachment anxiety influence subsequent quality of life, anxiety and depression in older adults?

Do loneliness, psychological flexibility, and interpersonal problems influence the relationship between psychological well-being and attachment anxiety?

How do loneliness, psychological flexibility, and interpersonal problems influence the relationship between psychological well-being and attachment anxiety?

1.4 ENDPOINTS

1.4.1 Primary Endpoint

The primary endpoint will be the factors that are associated with loneliness, quality of life and anxiety and depression in older people.

1.4.2 Secondary Endpoints

How the identified factors influence loneliness, anxiety, depression and quality of life.

2 STUDY DESIGN

This will be a cross-sectional study, which will require participants to complete five questionnaires once. While participants may be recruited through flu clinics or community groups, where they complete the questionnaire will be their own choice.

3 STUDY POPULATION

3.1 NUMBER OF PARTICIPANTS

This study aims to recruit 117 participants.

Participants will be recruited from November 2018 – June 2019.

The study will take place at GP practices, in the homes of participants, or where a participant chooses to access the online questionnaire.

3.2 INCLUSION CRITERIA

Aged 60 or older,
Able to read and understand the English language,
No cognitive deficits.

3.3 EXCLUSION CRITERIA

Aged 59 or younger,
Unable to read,
Cognitive deficit.

4 PARTICIPANT SELECTION AND ENROLMENT

4.1 IDENTIFYING PARTICIPANTS

Potential participants will not be identified by the research team.

Potential participants will be identified as follows:

District nurses-they will be requested to approach all of their patients aged 60 and over who meet the inclusion criteria, these will be identified by reviewing the community health index numbers of those they are visiting. Once a district nurse has identified someone who meets the age criteria, they will be asked to use their discretion as to whether they meet the remaining inclusion criteria and would be a suitable candidate for the study.

GP flu clinics-practice managers will be requested to distribute the questionnaire to potential participants aged 60 and over, these will be identified by reviewing the community health index numbers of those attending the clinics. Once a practice manager has identified someone who meets the age criteria, they will be asked to use their discretion as to whether they meet the remaining inclusion criteria and would be a suitable candidate for the study.

Online-Participants will be self-selecting.

Community groups-groups will be asked to inform their group members of the study.

4.2 CONSENTING PARTICIPANTS

Both the online participant information sheet and the paper questionnaire will include a tick box that participants will be required to tick to indicate that they wish to participate.

The length of time that potential participants will have to decide whether to participate will be open-ended. While those attending the GP flu clinics will be provided with the information leaflet and questionnaire while they are there, they will be advised to bring this home with them and read it carefully prior to deciding whether they wish to participate.

4.2.1 Withdrawal of Study Participants

Should a participant choose to withdraw prior to completing and submitting their questionnaire, they are free to do so. However, as we are not collecting personal information, it will not be possible to identify specific submissions and thus will not be possible to remove a participant's questionnaire at this point.

5 STUDY ASSESSMENTS

5.1 STUDY ASSESSMENTS

The only form of assessment in this study is the questionnaire, which is outlined in section 6, below.

6 DATA COLLECTION

Potential participants will be recruited from GP practices in NHS Dumfries and Galloway, during annual flu clinics, through community groups and through an online questionnaire, as follows:

Flu clinics
Links will be made with practice managers in local GP practices, which have already been involved with work with the local Older Adult Psychology Service. Practice managers at the GP practices have agreed to identify suitable participants and distribute the information leaflet and questionnaire to them, along with a stamped addressed envelope. Potential participants will be requested to read the leaflet and complete the questionnaire at a time of their choosing and return it using the attached envelope.

For those older people who are housebound, local district nurses will distribute the information leaflet and questionnaire to them when they are doing a house call to administer the flu jag. The envelope containing the questionnaire will be posted back to the researcher by either the district nurse or a member of the older person's support team.

Online questionnaire
In addition, participants will also be recruited using an online recruitment strategy, which will require participants to complete the questionnaire online. The Edinburgh University online survey management

site will be used to host the questionnaire. The link to the questionnaire, along with the associated information leaflet, will be distributed via twitter and Facebook. The local NHS D&G Facebook page will be used to host the link to the questionnaire. In terms of twitter, the questionnaire link will be tweeted to professional networks, such as the DCP and BPS, as well as independently run groups for older adults, such as Contact the Elderly and Men's Sheds, which may be harder to reach using other recruitment methods.

Community groups

Community groups specifically for older people, or those that include older people (such as Food Train, Food Train Friends) will also be used to recruit participants. Contact has been made with the co-ordinator of local third sector groups within Dumfries & Galloway, which already have links with the Older Adult Psychology Service. Links will also be made with Healthy Connections workers, from the Loneliness Project in order to identify further potential participants.

Data will be collected at one point in time. The data will be collected via self-administered questionnaires, which will be either paper or online.

Participants recruited from the flu clinics will be provided with a paper version of the questionnaire, however, should they wish to do so, they can access the online questionnaire, via the link in the participant information leaflet. The remainder of the study will be carried out through the online questionnaire. The online questionnaire will include a function that will require participants to complete all items prior to being able to submit it.

The following measures will be used:
Comprehensive assessment of Acceptance and Commitment Therapy processes (CompACT; Francis, Dawson, & Golijani-Moghaddam, 2016*)* This is a 23-item measure of psychological flexibility consisting of three sub-scales, namely openness to experience, behavioural awareness and valued action. Cronbach's alpha for the CompACT is 0.91. In terms of validity of the measure, it has good convergent validity when compared to other established ACT process measures (r=0.79), similarly, it has large positive correlations with the DASS-21, a measure of psychological difficulties (rs = .57-.65), indicating good concurrent validity.

Inventory of Interpersonal Problems (Horowitz, Rosenberg, Baer, Ureño & Villaseñor, 1988)
The IIP is a 32-item measure of distress due to interpersonal processes, which map onto the octants of the Interpersonal Circumplex. The scale consists of eight sub-scales: assertive, sociable, supportive, dependent, caring, aggressive, involved and open. Cronbach's alpha for the IIP-32 is 0.86. Internal consistency for the sub-scales ranges from .70-.88.

Relationship Awareness Scale-Relational Anxiety sub-scale (Snell, 1998)
The relational anxiety sub-scale of the RAS, consists of nine items, Cronbach's alpha for the scale is 0.88, indicating good internal consistency. In terms of internal reliability, this is reported to be good. This sub-scale addresses the extent to which someone experiences anxiety and discomfort in close relationships.

UCLA Loneliness Scale-8 item (Hays & DiMatteo, 1987)

The UCLA Loneliness Scale, eight-item version is a measure of loneliness, based on the longer 20-item UCLA loneliness scale. In terms of the reliability and validity of the measure, findings suggest it has good internal consistency, with a Cronbach's alpha of .84. The content of this scale reflects perceived loneliness, based on the difference between desired and actual social contact, with higher scores indicating greater loneliness.

Hospital Anxiety & Depression Scale (Zigmond & Snaith, 1983)

The HADS is a 14-item measure for symptoms of anxiety and depression, which focuses on non-somatic indicators of anxiety and depression to allow for the identification of such difficulties in physically ill populations. Index score ≥7 is thought to indicate caseness for both the anxiety and depression sub-scales (Bambauer, Locke, Aupont, Mullan, & McLaughlin, 2005), with higher scores indicating greater anxiety or depression. *Older People's Quality of Life questionnaire-brief (Bowling, Hankins, Windle, Bilotta & Grant, 2013)*

The OPQoL-brief is a 13-item questionnaire developed to address factors associated with quality of life, specifically among older adults. Cronbach's alpha for the questionnaire items range from .84-.86, indicating good internal consistency. The scale on which this is based, has been shown to be more reliable and valid when compared to other quality of life measures (Bowling & Stenner, 2011) and also may have prognostic value in research within this population (Bilotta et al., 2001).

7 STATISTICS AND DATA ANALYSIS

7.1 SAMPLE SIZE CALCULATION

Using Green (1991), based on a medium effect size, suggests 117 participants would need to be included, where N=104+the number of predictors. This sample size would allow the individual constructs within the psychological flexibility and interpersonal problems measures, as described above, to be used as predictors, which may lead to more meaningful findings. This calculation is based on an alpha of .05 and power at .80. The choice of a medium effect size in the sample size calculation is based on research using similar approaches, namely Gerhart et al., (2014). However, as the calculations using Gerhart's work resulted in large effect sizes, a more conservative medium effect size was chosen, as this work will be sampling older adults as opposed to university students and some aspects will be less well researched in this population and thus there is less evidence available to support using a sample size based on an estimate of a large effect size. Additional research addressing and loneliness and interpersonal processes (Masi et al., 2011), was also used to inform the sample size calculation.

7.2 PROPOSED ANALYSES

Descriptive and comparative analysis will be carried out to provide information about the sample.

Correlation analysis will be carried out to identify which factors correlate highly with each other. The findings from this will be used to inform subsequent regression analysis.

Regression analysis will be used to develop models of the factors that influence quality of life, anxiety and depression within the older adult population. A number of models will be tested, to identify the one with the best fit. Potential models using conditional process analysis are as follows:

- Using attachment anxiety as the IV, examining its impact on QoL, anxiety and depression, using loneliness, interpersonal problems and psychological flexibility as potential mediators or moderators.
- Using attachment anxiety and interpersonal problems as the IV, examining their impact on loneliness, QoL, anxiety and depression using psychological flexibility as a mediator or moderator.

8 OVERSIGHT ARRANGEMENTS

8.1 INSPECTION OF RECORDS

Investigators and institutions involved in the study will permit trial related monitoring and audits on behalf of the sponsor, REC review, and regulatory inspection(s). In the event of audit or monitoring, the Investigator agrees to allow the representatives of the sponsor direct access to all study records and source documentation. In the event of regulatory inspection, the Investigator agrees to allow inspectors direct access to all study records and source documentation.

8.2 RISK ASSESSMENT

A study specific risk assessment will be performed by representatives of the co-sponsors, ACCORD monitors and the QA group, in accordance with ACCORD governance and sponsorship SOPs. Input will be sought from the Chief Investigator or designee. The outcomes of the risk assessment will form the basis of the monitoring plans and audit plans. The risk assessment outcomes will also indicate which risk adaptions (delete if no adaptations were possible) could be incorporated into to trial design.

8.3 STUDY MONITORING AND AUDIT

The ACCORD Sponsor Representative will assess the study to determine if an independent risk assessment is required. If required, the independent risk assessment will be carried out by the ACCORD Quality Assurance Group to determine if an audit should be performed before/during/after the study and, if so, at what frequency.

Risk assessment, if required, will determine if audit by the ACCORD QA group is required. Should audit be required, details will be captured in an audit plan. Audit of Investigator sites, study management activities and study collaborative units, facilities and 3rd parties may be performed.

9 GOOD CLINICAL PRACTICE

9.1 ETHICAL CONDUCT

The study will be conducted in accordance with the principles of the International Conference on Harmonisation Tripartite Guideline for Good Clinical Practice (ICH GCP).

Before the study can commence, all required approvals will be obtained and any conditions of approvals will be met.

9.2 INVESTIGATOR RESPONSIBILITIES

The Investigator is responsible for the overall conduct of the study at the site and compliance with the protocol and any protocol amendments. In accordance with the principles of ICH GCP, the following areas listed in this section are also the responsibility of the Investigator. Responsibilities may be delegated to an appropriate member of study site staff.

9.2.1 Informed Consent

The Investigator is responsible for ensuring informed consent is obtained before any protocol specific procedures are carried out. The decision of a participant to participate in clinical research is voluntary and should be based on a clear understanding of what is involved.

Participants will receive adequate written information – appropriate Participant Information and will be provided.

The participant will be given every opportunity to clarify any points they do not understand and, if necessary, ask for more information. The participant will be given sufficient time to consider the information provided. It should be emphasised that the participant may withdraw their consent to participate at any time up to return of the questionnaire without loss of benefits to which they otherwise would be entitled.

9.2.2 Study Site Staff

The Investigator must be familiar with the protocol and the study requirements. It is the Investigator's responsibility to ensure that all staff assisting with the study are adequately informed about the protocol and their trial related duties.

9.2.3 Data Recording

The Principal Investigator is responsible for the quality of the data recorded in the CRF at each Investigator Site.

9.2.4 GCP Training

The Principal Investigator completed GCP training in March 2018.

9.2.5 Confidentiality

All questionnaires will contain identifiable information to maintain participant confidentiality. All completed questionnaires will be kept in a secure storage area with limited access. The Investigator and study site staff involved with this study will not disclose or use for any purpose other than performance of the study, any data, record, or other unpublished, confidential information disclosed to those individuals for the purpose of the study. Prior written agreement from the sponsor or its designee must be obtained for the disclosure of any said confidential information to other parties.

9.2.6 Data Protection

All Investigators and study site staff involved with this study will comply with the requirements of the Data Protection Act 2018 with regard to the collection, storage, processing and disclosure of personal information and will uphold the Act's core principles. Access to collated participant data will be restricted to individuals from the research team treating the participants, representatives of the sponsor(s) and representatives of regulatory authorities.

Computers used to collate the data will have limited access measures via user names and passwords.

Published results will not contain any personal data that could allow identification of individual participants.

10 STUDY CONDUCT RESPONSIBILITIES

10.1 PROTOCOL AMENDMENTS

Any changes in research activity, except those necessary to remove an apparent, immediate hazard to the participant in the case of an urgent safety measure, must be reviewed and approved by the Chief Investigator.

Amendments will be submitted to a sponsor representative for review and authorisation before being submitted in writing to the appropriate REC, and local R&D for approval prior to participants being enrolled into an amended protocol.

10.2 MANAGEMENT OF PROTOCOL NON COMPLIANCE

Prospective protocol deviations, i.e. protocol waivers, will not be approved by the sponsors and therefore will not be implemented, except where necessary to eliminate an immediate hazard to study participants. If this necessitates a subsequent protocol amendment, this should be submitted to the REC, and local R&D for review and approval if appropriate.

Protocol deviations will be recorded in a protocol deviation log and logs will be submitted to the sponsors every 3 months. Each protocol violation will be reported to the sponsor within 3 days of becoming aware of the violation. All protocol deviation logs and violation forms should be emailed to QA@accord.scot

Deviations and violations are non-compliance events discovered after the event has occurred. Deviation logs will be maintained for each site in multi-centre studies. An alternative frequency of deviation log submission to the sponsors may be agreed in writing with the sponsors.

10.3 SERIOUS BREACH REQUIREMENTS

A serious breach is a breach which is likely to effect to a significant degree:

(a) the safety or physical or mental integrity of the participants of the trial; or

(b) the scientific value of the trial.

If a potential serious breach is identified by the Chief investigator, Principal Investigator or delegates, the co-sponsors (seriousbreach@accord.scot) must be notified within 24 hours. It is the responsibility of the co-sponsors to assess the impact of the breach on the scientific value of the trial, to determine whether the incident constitutes a serious breach and report to research ethics committees as necessary.

10.4 STUDY RECORD RETENTION

All study documentation will be kept for a minimum of 3 years from the protocol defined end of study point. When the minimum retention period has elapsed, study documentation will not be destroyed without permission from the sponsor.

10.5 END OF STUDY

The end of study is defined as the last participant's last visit.

The Investigators or the co-sponsor(s) have the right at any time to terminate the study for clinical or administrative reasons.

The end of the study will be reported to the REC, and R+D Office(s) and co-sponsors within 90 days, or 15 days if the study is terminated prematurely. The Investigators will inform participants of the

premature study closure and ensure that the appropriate follow up is arranged for all participants involved. End of study notification will be reported to the co-sponsors via email to resgov@accord.scot.

A summary report of the study will be provided to the REC within 1 year of the end of the study.

10.6 INSURANCE AND INDEMNITY

The co-sponsors are responsible for ensuring proper provision has been made for insurance or indemnity to cover their liability and the liability of the Chief Investigator and staff.

The following arrangements are in place to fulfil the co-sponsors' responsibilities:

- The Protocol has been designed by the Chief Investigator and researchers employed by the University and collaborators. The University has insurance in place (which includes no-fault compensation) for negligent harm caused by poor protocol design by the Chief Investigator and researchers employed by the University.
- Sites participating in the study will be liable for clinical negligence and other negligent harm to individuals taking part in the study and covered by the duty of care owed to them by the sites concerned. The co-sponsors require individual sites participating in the study to arrange for their own insurance or indemnity in respect of these liabilities.
- Sites which are part of the United Kingdom's National Health Service will have the benefit of NHS Indemnity.

11 REPORTING, PUBLICATIONS AND NOTIFICATION OF RESULTS

11.1 AUTHORSHIP POLICY

Ownership of the data arising from this study resides with the study team.

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